

Technical Documentation for Packaging according to Annex VII of Regulation (EU) 2025/40 (PPWR)

Product name: **Traumacel TAF**
Traumacel TAF Light
Traumacel FAM Strata
Traumacel FAM Trium
Traumacel FAM OcW
Traumacel NEW Dent
Traumastem TAF
Traumastem TAF Light
Traumastem FAM Strata
Traumastem FAM Trium
Traumastem FAM OcW
Traumastem NEW Dent

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1. List of Packaging Components

Primary packaging

Secondary packaging

Label for primary packaging

Thermal transfer ribbon

Printed paper box

Label for paper box

Label for paper box with UDI

Group packaging box

Label for group packaging box

Round blue label

Round green label

Transport carton

Label for transport box

Package leaflet / instructions for use

Transparent adhesive sealing tape

Stretch film

Polypropylene strapping

Bubble wrap

Paper void fill

2. Packaging Identification

2.1 Basic Identification Data

Packaging component	Intended use	Packaging category	Contact-sensitive packaging	EU market
Primary packaging	Forms part of the sterile barrier. Protective packaging that helps maintain product protection until use.	Inner packaging	Yes	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Secondary packaging	Forms part of the sterile barrier. Protective packaging that helps maintain product protection until use.	Inner packaging	Yes	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Label for primary packaging	Provides product identification, traceability and required labelling information.	Inner packaging	Yes	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Thermal transfer ribbon	Printing consumable used to print variable information on labels or packaging.		No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Paper box	Serves as sales-unit packaging; contains and protects the packaged product and carries product information.	Sales packaging	No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Label for paper box	Provides product identification,		No	BG, CZ, DE, ES, GR,

Packaging component	Intended use	Packaging category	Contact-sensitive packaging	EU market
	traceability and required labelling information.			HU, PL, PT, RO, SK, SI
Label for paper box with UDI	Provides product identification, traceability and required labelling information.		No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Group packaging box	Groups packaged units and protects them during storage, handling and transport.	Group packaging	No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Label for group packaging box	Provides product identification, traceability and required labelling information.		No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Transport carton	Groups packaged units and protects them during storage, handling and transport.	Transport packaging	No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Label for transport carton	Provides product identification, traceability and required labelling information.		No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Package leaflet / instructions for use	Provides user information, instructions for use, warnings and precautions.		No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Round blue label	Indicates finished batch		No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Round green	Indicates released		No	BG, CZ, DE, ES, GR,

Packaging component	Intended use	Packaging category	Contact-sensitive packaging	EU market
label	batch			HU, PL, PT, RO, SK, SI
Transparent adhesive sealing tape	Seals outer cartons for storage, handling and transport.	Transport packaging	No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Stretch film	Protects carton boxes during transport.	Transport packaging	No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Polypropylene strapping	Holds carton boxes during transport on wooden pallet	Transport packaging	No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Bubble wrap	Cushions products and protects them against impact and movement.	Transport packaging	No	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI
Paper void fill	Fills empty space and prevents product movement inside the box.	Transport packaging	NO	BG, CZ, DE, ES, GR, HU, PL, PT, RO, SK, SI

2.2 Variants of Packaging Components

Packaging component	Variant
Primary packaging	3 sizes: 105 × 70 mm; 155 x 120 mm; 140 x 35 mm
Secondary packaging	2 sizes: 140 x 105 mm; 210 × 140 mm
Label for primary packaging	1 size: 100 x 23 mm
Paper box	5 sizes: 140 x 115 x 60 mm; 222 × 153 × 82 mm; 142 × 118 × 82 mm; 222 x 153 x 62
Label for paper box	2 sizes: 36 × 70 mm; 36 × 30 mm
UDI label for paper box	1 size: 36 × 30 mm

Group packaging carton	3 sizes: 315 × 229 × 342 mm; 241 × 291 × 342 mm; 297 x 189 x 245 mm
Label for group packaging carton	1 size: 148 × 105 mm
Transport carton	2 sizes: 770 × 390 × 295 mm; 770 × 390 × 330 mm;
Label for transport carton	1 size: 148 × 105 mm
Instructions for Use (IFU)	3 formats: 210 x 297 mm; 210 x 270 mm; 620 x 370 mm
Round blue label	1 format: 14 mm diameter
Round green label	1 format: 14 mm diameter
Transparent adhesive sealing tape	1 type: width 50 mm
Stretch film	1 type: width 500 mm, thickness 12 µm
Polypropylene strapping	1 type: width 12 mm, thickness 0,5 mm
Bubble wrap	
Paper void fill	

2.3 Identification Codes of Packaging Components

Not all packaging components have individual identification codes, as certain packaging materials cannot be practically marked or printed.

REF	Name of the product	Size	Primary packaging	Secondary packaging	Paper box	Label on paper box	Label on paper box with UDI	Group packaging box	Label for group packaging box	Transport carton	Label for transport carton	Package leaflet / instructions for use
10138	Traumacel TAF	1,5 cm x 5 cm	101381/4	101382/4	mz808/1	101385/3	101386/3	mz877	101388/4	mz869	1013810/4	mz1223/1
10139	Traumacel TAF	5 cm x 7,5 cm	101391/4	101392/4	mz808/1	101395/3	101396/3	mz877	101398/4	mz869	1013910/4	mz1223/1
10274	Traumacel TAF	5 cm x 12,5 cm	102741/4	102742/4	mz808/1	102745/3	102746/3	mz877	102748/4	mz869	1027410/4	mz1223/1
10275	Traumacel TAF	5 cm x 35 cm	102751/4	102752/4	mz808/1	102755/3	102756/3	mz877	102758/4	mz869	1027510/4	mz1223/1
10272	Traumacel TAF	10 cm x 20 cm	102721/4	102722/4	mz808/1	102725/3	102726/3	mz877	102728/4	mz869	1027210/4	mz1223/1
60001	Traumacel TAF	1,25 cm x 5 cm	600011/4	600012/4	mz808/1	600015/3	600016/3	mz877	600018/4	mz869	6000110/4	mz1223/1
60002	Traumacel TAF	2,5 cm x 2,5 cm	600021/4	600022/4	mz808/1	600025/3	600026/3	mz877	600028/4	mz869	6000210/4	mz1223/1
60003	Traumacel TAF	2,5 cm x 9 cm	600031/4	600032/4	mz808/1	600035/3	600036/3	mz877	600038/4	mz869	6000310/4	mz1223/1
60004	Traumacel TAF	2,5 cm x 5 cm	600041/4	600042/4	mz808/1	600045/3	600046/3	mz877	600048/4	mz869	6000410/4	mz1223/1
60005	Traumacel TAF	5 cm x 10 cm	600051/4	600052/4	mz808/1	600055/3	600056/3	mz877	600058/4	mz869	6000510/4	mz1223/1
60006	Traumacel TAF	7,5 cm x 10 cm	600061/4	600062/4	mz808/1	600065/3	600066/3	mz877	600068/4	mz869	6000610/4	mz1223/1
60007	Traumacel TAF	10 cm x 10 cm	600071/4	600072/4	mz808/1	600075/3	600076/3	mz877	600078/4	mz869	6000710/4	mz1223/1
60008	Traumacel TAF	15 cm x 25 cm	600081/4	600082/4	mz808/1	600085/3	600086/3	mz877	600088/4	mz869	6000810/4	mz1223/1
60009	Traumacel TAF	15,2 cm x 22,9 cm	600091/4	600092/4	mz808/1	600095/3	600096/3	mz877	600098/4	mz869	6000910/4	mz1223/1
60010	Traumacel TAF	2 cm x 5 cm	600101/4	600102/4	mz808/1	600105/3	600106/3	mz877	600108/4	mz869	6001010/4	mz1223/1
60011	Traumacel TAF	7 cm x 5 cm	600111/4	600112/4	mz808/1	600115/3	600116/3	mz877	600118/4	mz869	6001110/4	mz1223/1
60012	Traumacel TAF	7 cm x 10 cm	600121/4	600122/4	mz808/1	600125/3	600126/3	mz877	600128/4	mz869	6001210/4	mz1223/1
60013	Traumacel TAF	1 cm x 5 cm	600131/4	600132/4	mz808/1	600135/3	600136/3	mz877	600138/4	mz869	6001310/4	mz1223/1
60014	Traumacel TAF	15 cm x 23 cm	600141/4	600142/4	mz808/1	600145/3	600146/3	mz877	600148/4	mz869	6001410/4	mz1223/1
60015	Traumacel TAF	2,6 cm x 2,6 cm	600151/4	600152/4	mz808/1	600155/3	600156/3	mz877	600158/4	mz869	6001510/4	mz1223/1
60016	Traumacel TAF	2,5 cm x 5,1 cm	600161/4	600162/4	mz808/1	600165/3	600166/3	mz877	600168/4	mz869	6001610/4	mz1223/1
10295	Traumacel TAF Light	1,5 cm x 5 cm	102951/4	102952/4	mz1013/1	102955/3	102956/3	mz877	102958/4	mz869	1029510/4	mz1223/1

10296	Traumacel TAF Light	5 cm x 7,5 cm	102961/4	102962/4	mz1013/1	102965/3	102966/3	mz877	102968/4	mz869	1029610/4	mz1223/1
10297	Traumacel TAF Light	5 cm x 12,5 cm	102971/4	102972/4	mz1013/1	102975/3	102976/3	mz877	102978/4	mz869	1029710/4	mz1223/1
10298	Traumacel TAF Light	5 cm x 35 cm	102981/4	102982/4	mz1013/1	102985/3	102986/3	mz877	102988/4	mz869	1029810/4	mz1223/1
10299	Traumacel TAF Light	10 cm x 20 cm	102991/4	102992/4	mz1013/1	102995/3	102996/3	mz877	102998/4	mz869	1029910/4	mz1223/1
60017	Traumacel TAF Light	1,25 cm x 5 cm	600171/4	600172/4	mz1013/1	600175/3	600176/3	mz877	600178/4	mz869	6001710/4	mz1223/1
60018	Traumacel TAF Light	2,5 cm x 2,5 cm	600181/4	600182/4	mz1013/1	600185/3	600186/3	mz877	600188/4	mz869	6001810/4	mz1223/1
60019	Traumacel TAF Light	2,5 cm x 9 cm	600191/4	600192/4	mz1013/1	600195/3	600196/3	mz877	600198/4	mz869	6001910/4	mz1223/1
60020	Traumacel TAF Light	2,5 cm x 5 cm	600201/4	600202/4	mz1013/1	600205/3	600206/3	mz877	600208/4	mz869	6002010/4	mz1223/1
60021	Traumacel TAF Light	5 cm x 10 cm	600211/4	600212/4	mz1013/1	600215/3	600216/3	mz877	600218/4	mz869	6002110/4	mz1223/1
60022	Traumacel TAF Light	7,5 cm x 10 cm	600221/4	600222/4	mz1013/1	600225/3	600226/3	mz877	600228/4	mz869	6002210/4	mz1223/1
60023	Traumacel TAF Light	10 cm x 10 cm	600231/4	600232/4	mz1013/1	600235/3	600236/3	mz877	600238/4	mz869	6002310/4	mz1223/1
60024	Traumacel TAF Light	15 cm x 25 cm	600241/4	600242/4	mz1013/1	600245/3	600246/3	mz877	600248/4	mz869	6002410/4	mz1223/1
60025	Traumacel TAF Light	15,2 cm x 22,9 cm	600251/4	600252/4	mz1013/1	600255/3	600256/3	mz877	600258/4	mz869	6002510/4	mz1223/1
60026	Traumacel TAF Light	2 cm x 5 cm	600261/4	600262/4	mz1013/1	600265/3	600266/3	mz877	600268/4	mz869	6002610/4	mz1223/1
60027	Traumacel TAF Light	7 cm x 5 cm	600271/4	600272/4	mz1013/1	600275/3	600276/3	mz877	600278/4	mz869	6002710/4	mz1223/1
60028	Traumacel TAF Light	7 cm x 10 cm	600281/4	600282/4	mz1013/1	600285/3	600286/3	mz877	600288/4	mz869	6002810/4	mz1223/1
60029	Traumacel TAF Light	1 cm x 5 cm	600291/4	600292/4	mz1013/1	600295/3	600296/3	mz877	600298/4	mz869	6002910/4	mz1223/1
60030	Traumacel TAF Light	15 cm x 23 cm	600301/4	600302/4	mz1013/1	600305/3	600306/3	mz877	600308/4	mz869	6003010/4	mz1223/1
60031	Traumacel TAF Light	2,6 cm x 2,6 cm	600311/4	600312/4	mz1013/1	600315/3	600316/3	mz877	600318/4	mz869	6003110/4	mz1223/1
60032	Traumacel TAF Light	2,5 cm x 5,1 cm	600321/4	600322/4	mz1013/1	600325/3	600326/3	mz877	600328/4	mz869	6003210/4	mz1223/1
10230	Traumastem TAF	1,5 cm x 5 cm	102301/4	102302/5	mz809/1	102305/3	102306/3	mz877	102308/5	mz869	1023010/5	mz1225/1
10231	Traumastem TAF	5 cm x 7,5 cm	102311/4	102312/5	mz809/1	102315/3	102316/3	mz877	102318/5	mz869	1023110/5	mz1225/1
10232	Traumastem TAF	5 cm x 12,5 cm	102321/4	102322/5	mz809/1	102325/3	102326/3	mz877	102328/5	mz869	1023210/5	mz1225/1
10233	Traumastem TAF	5 cm x 35 cm	102331/4	102332/5	mz809/1	102335/3	102336/3	mz877	102338/5	mz869	1023310/5	mz1225/1
10234	Traumastem TAF	10 cm x 20 cm	102341/4	102342/5	mz809/1	102345/3	102346/3	mz877	102348/5	mz869	1023410/5	mz1225/1
10204	Traumastem TAF	1,25 cm x 5 cm	102041/4	102042/5	mz809/1	102045/3	102046/3	mz877	102048/5	mz869	1020410/5	mz1225/1

10195	Traumastem TAF	2,5 cm x 2,5 cm	101951/4	101952/5	mz809/1	101955/3	101956/3	mz877	101958/5	mz869	1019510/5	mz1225/1
10196	Traumastem TAF	2,5 cm x 9 cm	101961/4	101962/5	mz809/1	101965/3	101966/3	mz877	101968/5	mz869	1019610/5	mz1225/1
10244	Traumastem TAF	2,5 cm x 5 cm	102441/4	102442/5	mz809/1	102445/3	102446/3	mz877	102448/5	mz869	1024410/5	mz1225/1
10245	Traumastem TAF	5 cm x 10 cm	102451/4	102452/5	mz809/1	102455/3	102456/3	mz877	102458/5	mz869	1024510/5	mz1225/1
10194	Traumastem TAF	7,5 cm x 10 cm	101941/4	101942/5	mz809/1	101945/3	101946/3	mz877	101948/5	mz869	1019410/5	mz1225/1
10236	Traumastem TAF	10 cm x 10 cm	102361/4	102362/5	mz809/1	102365/3	102366/3	mz877	102368/5	mz869	1023610/5	mz1225/1
10028	Traumastem TAF	15 cm x 25 cm	100281/4	100282/5	mz809/1	100285/3	100286/3	mz877	100288/5	mz869	1002810/5	mz1225/1
10334	Traumastem TAF	15,2 cm x 22,9 cm	103341/4	103342/5	mz809/1	103345/3	103346/3	mz877	103348/5	mz869	1033410/5	mz1225/1
60033	Traumastem TAF	2 cm x 5 cm	600331/4	600332/5	mz809/1	600335/3	600336/3	mz877	600338/5	mz869	6003310/5	mz1225/1
60034	Traumastem TAF	5 cm x 7 cm	600341/4	600342/5	mz809/1	600345/3	600346/3	mz877	600348/5	mz869	6003410/5	mz1225/1
10320	Traumastem TAF	7 cm x 10 cm	103201/4	103202/5	mz809/1	103205/3	103206/3	mz877	103208/5	mz869	1032010/5	mz1225/1
60035	Traumastem TAF	1 cm x 5 cm	600351/4	600352/5	mz809/1	600355/3	600356/3	mz877	600358/5	mz869	6003510/5	mz1225/1
10319	Traumastem TAF	15 cm x 23 cm	103191/4	103192/5	mz809/1	103195/3	103196/3	mz877	103198/5	mz869	1031910/5	mz1225/1
60036	Traumastem TAF	2,6 cm x 2,6 cm	600361/4	600362/5	mz809/1	600365/3	600366/3	mz877	600368/5	mz869	6003610/5	mz1225/1
60037	Traumastem TAF	2,5 cm x 5,1 cm	600371/4	600372/5	mz809/1	600375/3	600376/3	mz877	600378/5	mz869	6003710/5	mz1225/1
10224	Traumastem TAF Light	1,5 cm x 5 cm	102241/4	102242/5	mz810/1	102245/3	102246/3	mz877	102248/5	mz869	1022410/5	mz1225/1
10225	Traumastem TAF Light	5 cm x 7,5 cm	102251/4	102252/5	mz810/1	102255/3	102256/3	mz877	102258/5	mz869	1022510/5	mz1225/1
10228	Traumastem TAF Light	5 cm x 12,5 cm	102281/4	102282/5	mz810/1	102285/3	102286/3	mz877	102288/5	mz869	1022810/5	mz1225/1
10226	Traumastem TAF Light	5 cm x 35 cm	102261/4	102262/5	mz810/1	102265/3	102266/3	mz877	102268/5	mz869	1022610/5	mz1225/1
10227	Traumastem TAF Light	10 cm x 20 cm	102271/4	102272/5	mz810/1	102275/3	102276/3	mz877	102278/5	mz869	1022710/5	mz1225/1
10326	Traumastem TAF Light	1,25 cm x 5 cm	103261/4	103262/5	mz810/1	103265/3	103266/3	mz877	103268/5	mz869	1032610/5	mz1225/1
10333	Traumastem TAF Light	2,5 cm x 2,5 cm	103331/4	103332/5	mz810/1	103335/3	103336/3	mz877	103338/5	mz869	1033310/5	mz1225/1
10246	Traumastem TAF Light	2,5 cm x 9 cm	102461/4	102462/5	mz810/1	102465/3	102466/3	mz877	102468/5	mz869	1024610/5	mz1225/1
60038	Traumastem TAF Light	2,5 cm x 5 cm	600381/4	600382/5	mz810/1	600385/3	600386/3	mz877	600388/5	mz869	6003810/5	mz1225/1
10258	Traumastem TAF Light	5 cm x 10 cm	102581/4	102582/5	mz810/1	102585/3	102586/3	mz877	102588/5	mz869	1025810/5	mz1225/1
10278	Traumastem TAF Light	7,5 cm x 10 cm	102781/4	102782/5	mz810/1	102785/3	102786/3	mz877	102788/5	mz869	1027810/5	mz1225/1

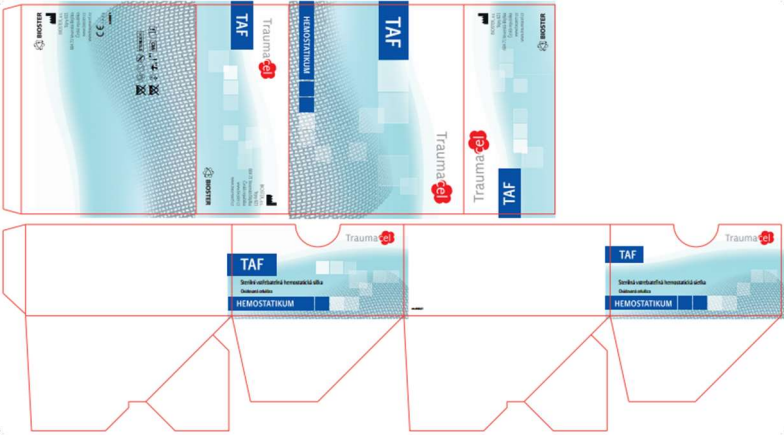
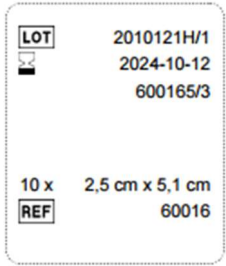
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60039	Traumastem TAF Light	15 cm x 25 cm	600391/4	600392/5	mz810/1	600395/3	600396/3	mz877	600398/5	mz869	6003910/5	mz1225/1
60040	Traumastem TAF Light	15,2 cm x 22,5 cm	600401/4	600402/5	mz810/1	600405/3	600406/3	mz877	600408/5	mz869	6004010/5	mz1225/1
10208	Traumastem TAF Light	2 cm x 5 cm	102081/4	102082/5	mz810/1	102085/3	102086/3	mz877	102088/5	mz869	1020810/5	mz1225/1
10322	Traumastem TAF Light	5 cm x 7 cm	103221/4	103222/5	mz810/1	103225/3	103226/3	mz877	103228/5	mz869	1032210/5	mz1225/1
10256	Traumastem TAF Light	7 cm x 10 cm	102561/4	102562/5	mz810/1	102565/3	102566/3	mz877	102568/5	mz869	1025610/5	mz1225/1
10321	Traumastem TAF Light	1 cm x 5 cm	103211/4	103212/5	mz810/1	103215/3	103216/3	mz877	103218/5	mz869	1032110/5	mz1225/1
10332	Traumastem TAF Light	15 cm x 23 cm	103321/4	103322/5	mz810/1	103325/3	103326/3	mz877	103328/5	mz869	1033210/5	mz1225/1
10203	Traumastem TAF Light	2,6 cm x 2,6 cm	102031/4	102032/5	mz810/1	102035/3	102036/3	mz877	102038/5	mz869	1020310/5	mz1225/1
10324	Traumastem TAF Light	2,5 cm x 5,1 cm	103241/4	103242/5	mz810/1	103245/3	103246/3	mz877	103248/5	mz869	1032410/5	mz1225/1
10127	Traumacel FAM Strata	2,5 cm x 5 cm	101271/4	101272/4	mz951/1	101275/3	101276/3	mz1194	101278/4	mz875	1012710/4	mz1223/1
10128	Traumacel FAM Strata	5 cm x 10 cm	101281/4	101282/4	mz950/1	101285/3	101286/3	mz1094	101288/4	mz875	1012810/4	mz1223/1
10129	Traumacel FAM Strata	10 cm x 10 cm	101291/4	101292/4	mz950/1	101295/3	101296/3	mz1094	101298/4	mz875	1012910/4	mz1223/1
60116	Traumacel FAM Strata	5 cm x 7,5 cm	601161/4	601162/4	mz950/1	601165/3	601166/3	mz1094	601168/4	mz875	6011610/4	mz1223/1
10131	Traumacel FAM Trium	2,5 cm x 5 cm	101311/4	101312/4	mz947/1	101315/3	101316/3	mz1194	101318/4	mz875	1013110/4	mz1223/1
10132	Traumacel FAM Trium	5 cm x 10 cm	101321/4	101322/4	mz946/1	101325/3	101326/3	mz1094	101328/4	mz875	1013210/4	mz1223/1
10133	Traumacel FAM Trium	10 cm x 10 cm	101331/4	101332/4	mz946/1	101335/3	101336/3	mz1094	101338/4	mz875	1013310/4	mz1223/1
60117	Traumacel FAM Trium	5 cm x 7,5 cm	601171/4	601172/4	mz946/1	601175/3	601176/3	mz1094	601178/4	mz875	6011710/4	mz1223/1
10121	Traumacel FAM OcW	2 g	101211/4	101212/4	mz944/1	101215/3	101216/3	mz1094	101218/4	mz875	1012110/4	mz1223/1
10115	Traumacel NEW Dent	1 cm x 1,5 cm	101151/4	x	mz959/1	101155/3	101156/3	mz877	101158/4	mz869	1011510/4	mz1224/1
09011	Traumastem FAM Strata	2,5 cm x 5 cm	090111/4	090112/5	mz953/1	090115/3	090116/3	mz1194	090118/5	mz875	0901110/5	mz1225/1
09012	Traumastem FAM Strata	5 cm x 10 cm	090121/4	090122/5	mz952/1	090125/3	090126/3	mz1094	090128/5	mz875	0901210/5	mz1225/1
09013	Traumastem FAM Strata	10 cm x 10 cm	090131/4	090132/5	mz952/1	090135/3	090136/3	mz1094	090138/5	mz875	0901310/5	mz1225/1
60118	Traumastem FAM Strata	5 cm x 7,5 cm	601181/4	601182/5	mz952/1	601185/3	601186/3	mz1094	601188/5	mz875	6011810/5	mz1225/1
09014	Traumastem FAM Trium	2,5 cm x 5 cm	090141/4	090142/5	mz949/1	090145/3	090146/3	mz1194	090148/5	mz875	0901410/5	mz1225/1
09016	Traumastem FAM Trium	5 cm x 10 cm	090161/4	090162/5	mz948/1	090165/3	090166/3	mz1094	090168/5	mz875	0901610/5	mz1225/1

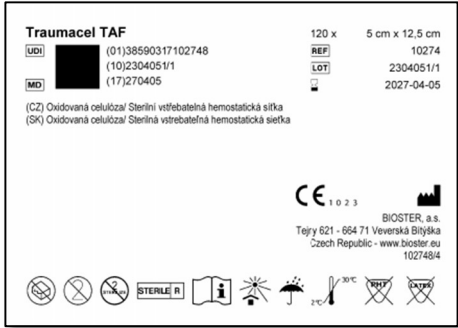
09015	Traumastem FAM Trium	10 cm x 10 cm	090151/4	090152/5	mz948/1	090155/3	090156/3	mz1094	090158/5	mz875	0901510/5	mz1225/1
60119	Traumastem FAM Trium	5 cm x 7,5 cm	601191/4	601192/5	mz948/1	601195/3	601196/3	mz1094	601198/5	mz875	6011910/5	mz1225/1
09008	Traumastem FAM OcW	2 g	090081/4	090082/5	mz945/1	090085/3	090086/3	mz1094	090088/5	mz875	0900810/5	mz1225/1
09000	Traumastem NEW Dent	1 cm x 1,5 cm	090001/4	x	mz960/1	090005/3	090006/3	mz877	090008/4	mz869	0900010/4	mz1226/1

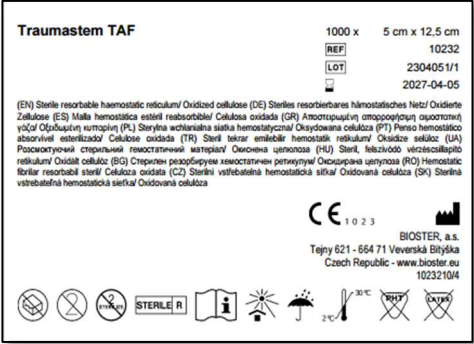
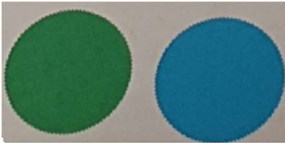
3. Description of the Packaging, Its Intended Purpose, Design Documentation and Material Composition

3.1 Traumacel TAF

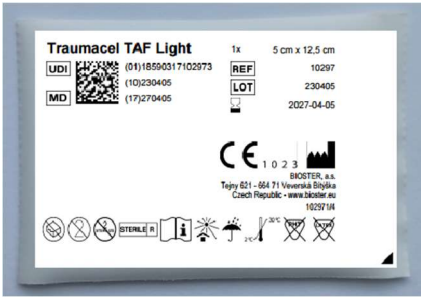
Primary packaging	Sterile pouch Packaging material -Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed primary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of Use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols 
Secondary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed tertiary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols, composition. 

Printed paper box	The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit. Material: Printed cardboard  Contents of one sales package: 10 pcs
Label for the paper box	Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number Material: Polyester 
UDI Label for the Paper Box	Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code Material: Paper + adhesive 
Group Packaging Carton	The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units. Material: Corrugated paper

	
Group Packaging Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols storage symbols Material : paper + adhesive 
Transport carton Transparent adhesive sealing tape Stretch film Polypropylene strapping Bubble wrap Paper void fill	Material: Corrugated paper  
Transport carton label	Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols Material: Paper + adhesive

	
Round blue label Round green label	The labels provide visual identification of the product/package release status. They are placed on the Group packaging box. Material: Paper + adhesive 

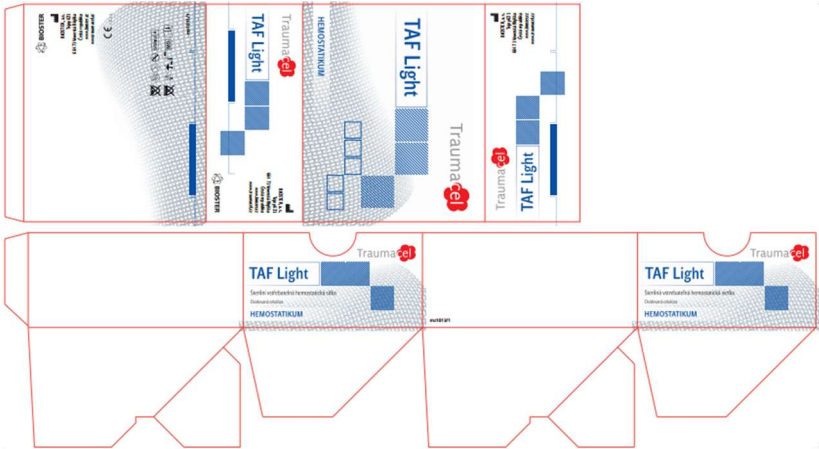
3.2 Traumacel TAF Light

Primary packaging	Sterile pouch Packaging material -Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed primary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of Use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols 
Secondary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed tertiary package includes: REF number, product name, product size

batch number (LOT), expiry date UDI – Unit of use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols, composition.

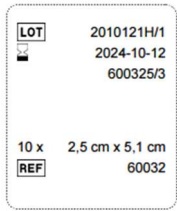


The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit.
Material: Printed cardboard

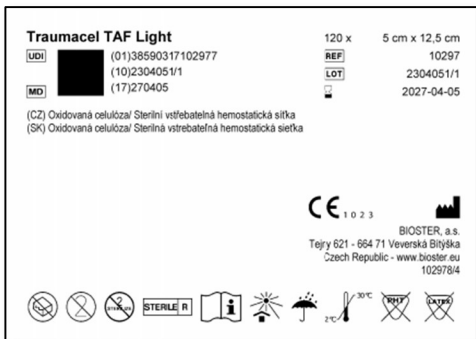


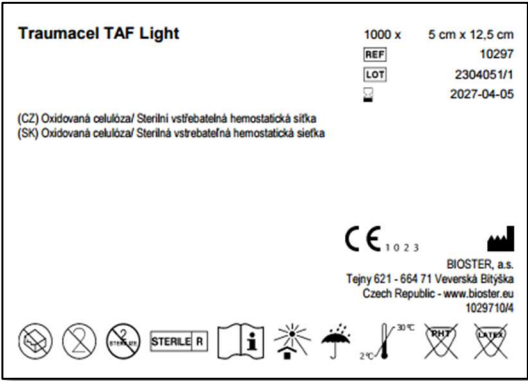
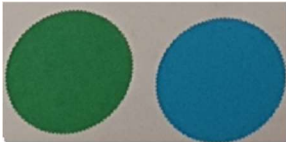
Contents of one sales package: 10 pcs

Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number
Material: Polyester

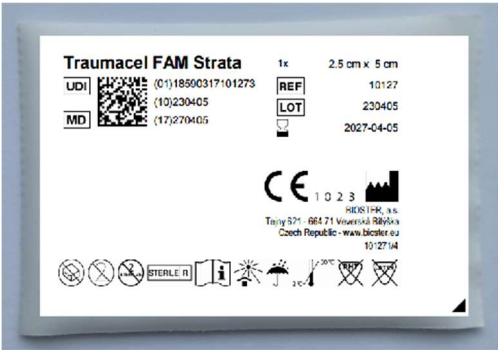


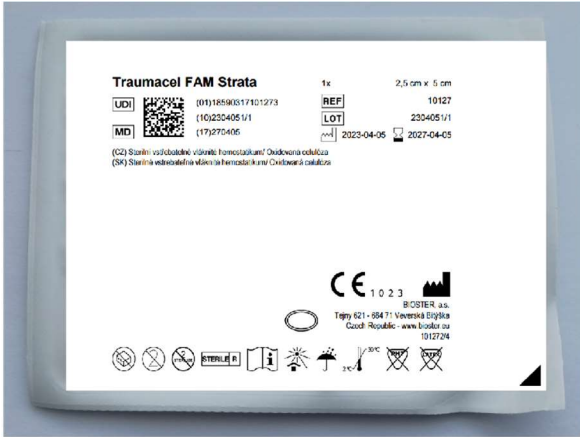
Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code

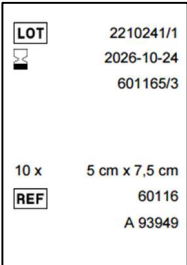
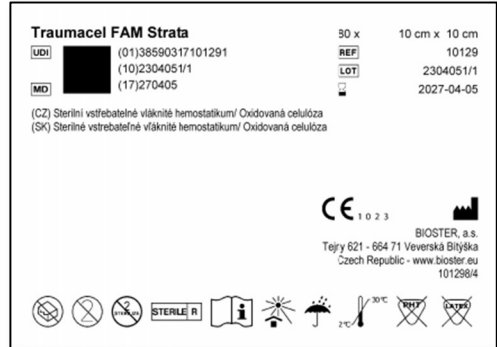
	Material: Paper + adhesive 
Group Packaging Carton	The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units. Material: Corrugated paper 
Group Packaging Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols storage symbols Material : paper + adhesive 
Transport carton Transparent adhesive sealing tape Stretch film Polypropylene strapping Bubble wrap Paper void fill	Material: Corrugated paper  

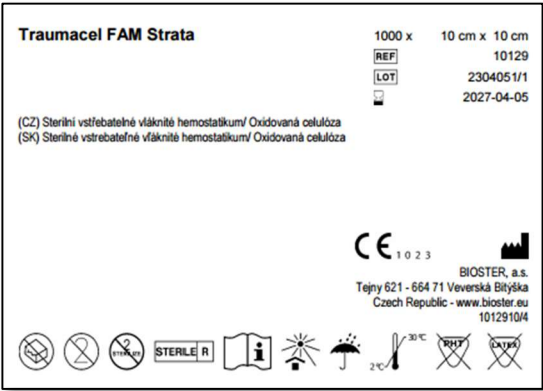
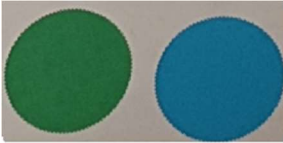
Transport carton label	Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols Material: Paper + adhesive 
Round blue label Round green label	The labels provide visual identification of the product/package release status. They are placed on the Group packaging box. Material: Paper + adhesive 

3.3 Traumacel FAM Strata

Primary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed primary package includes: REF number, product name, product size, batch number (LOT), expiry date UDI – Unit of Use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols 
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Secondary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed tertiary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols, composition. 
Printed paper box	The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit. Material: Printed cardboard  Contents of one sales package: 10 pcs
Label for the paper box	Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number Material: Polyester

	
UDI Label for the Paper Box	Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code Material: Paper + adhesive 
Group Packaging Carton	The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units. Material: Corrugated paper 
Group Packaging Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols storage symbols Material : paper + adhesive 

Transport carton Transparent adhesive sealing tape Stretch film Polypropylene strapping Bubble wrap Paper void fill	Material: Corrugated paper  
Transport carton label	Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols Material: Paper + adhesive 
Round blue label Round green label	The labels provide visual identification of the product/package release status. They are placed on the Group packaging box. Material: Paper + adhesive 

3.4 Traumacel FAM Trium

Primary packaging	Sterile pouch Packaging material -Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed primary package includes: REF number, product name, product size
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batch number (LOT), expiry date UDI – Unit of Use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols



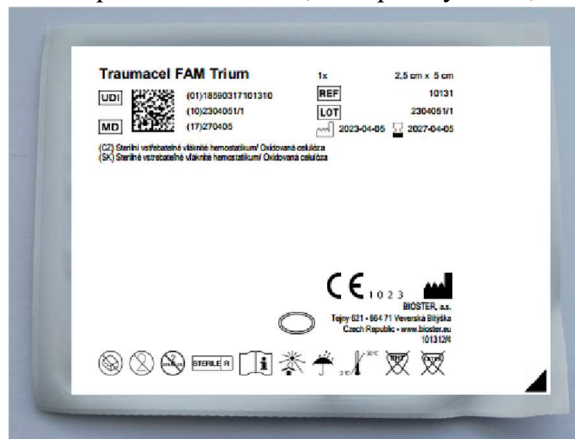
Sterile pouch

Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA

Material composition: PA/PE 3090 (polyamide, polyethylene)

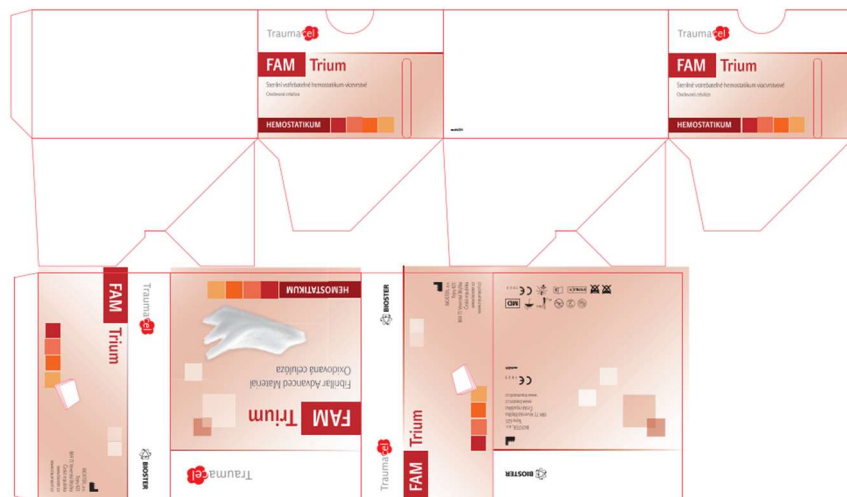
MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1

The printed tertiary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols, composition.



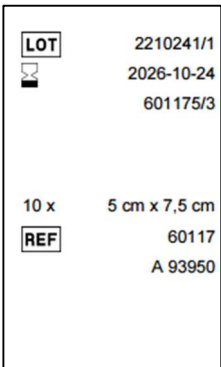
Secondary packaging

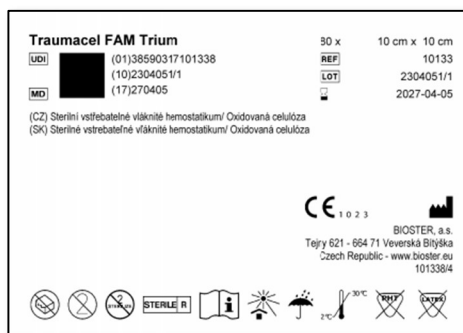
The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit.
Material: Printed cardboard



Printed paper box

Contents of one sales package: 10 pcs

Label for the paper box	Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number Material: Polyester 
UDI Label for the Paper Box	Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code Material: Paper + adhesive 
Group Packaging Carton	The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units. Material: Corrugated paper 
Group Packaging Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols, storage symbols Material : paper + adhesive



Transport carton
Transparent adhesive sealing tape
Stretch film
Polypropylene strapping
Bubble wrap
Paper void fill

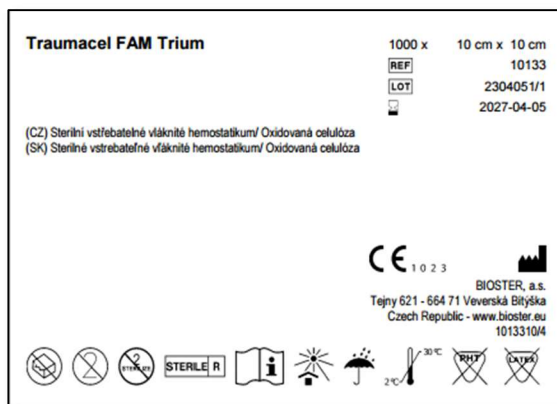
Material: Corrugated paper



Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols

Material: Paper + adhesive

Transport carton label



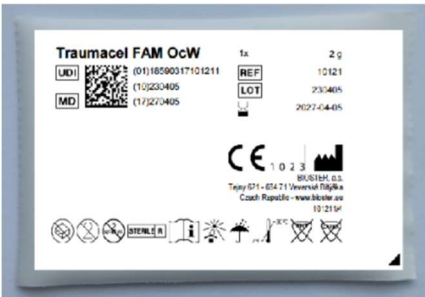
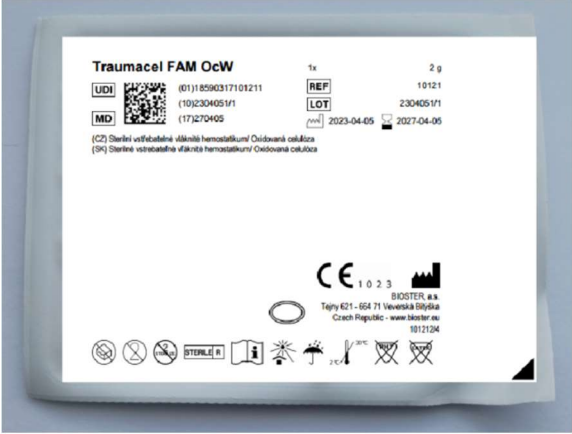
The labels provide visual identification of the product/package release status. They are placed on the Group packaging box.

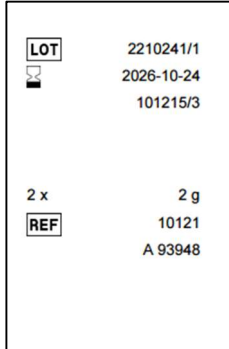
Material: Paper + adhesive

Round blue label
Round green label

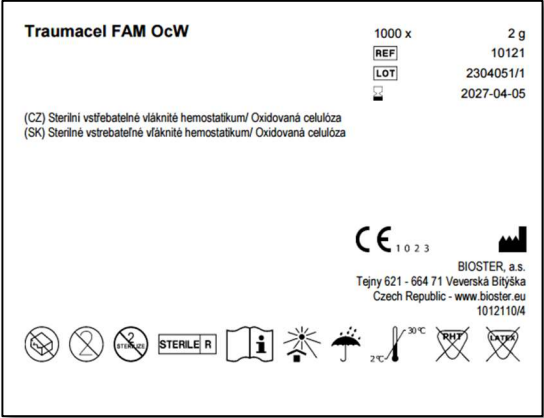
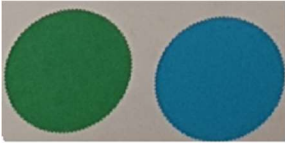


3.5 Traumacel FAM OcW

Primary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed primary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of Use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols 
Secondary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed tertiary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols, composition. 
Printed paper box	The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit. Material: Printed cardboard

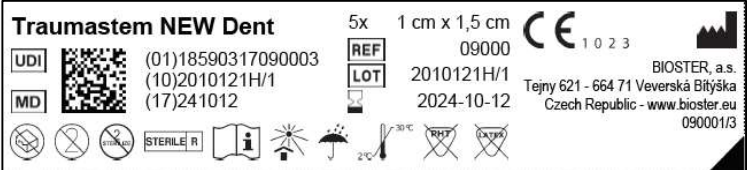
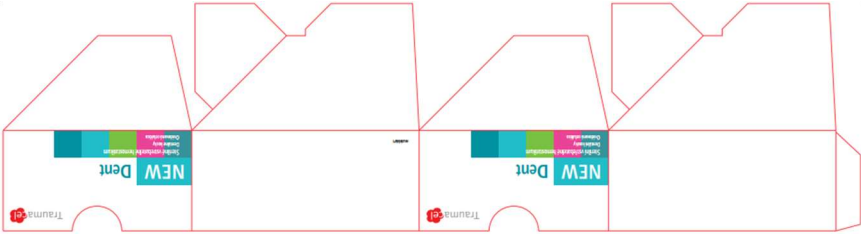
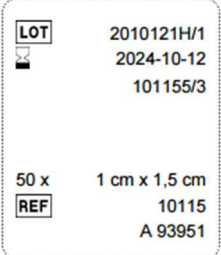
	 Contents of one sales package: 10 pcs
Label for the paper box	Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number Material: Polyester 
UDI Label for the Paper Box	Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code Material: Paper + adhesive 
Group Packaging Carton	The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units. Material: Corrugated paper

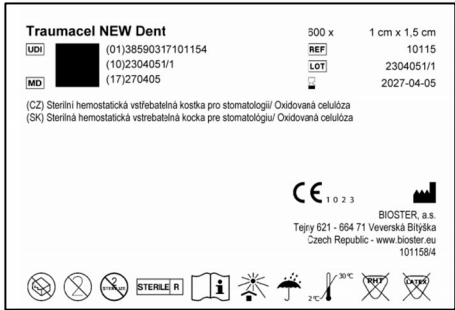
	
Group Packaging Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols storage symbols Material : paper + adhesive 
Transport carton Transparent adhesive sealing tape Stretch film Polypropylene strapping Bubble wrap Paper void fill	Material: Corrugated paper  
Transport carton label	Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols Material: Paper + adhesive

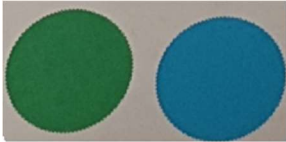
	
Round blue label Round green label	The labels provide visual identification of the product/package release status. They are placed on the Group packaging box. Material: Paper + adhesive 

3.6 Traumacel NEW Dent

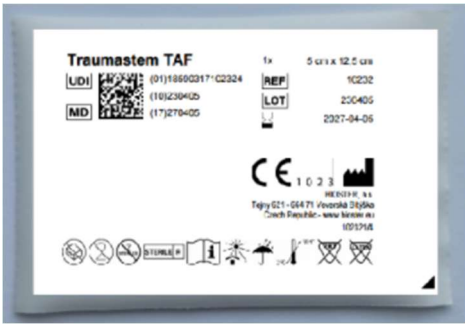
Primary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 
Label for primary packaging	The label contains: REF number, product name, product size, batch number (LOT), expiry date UDI – Unit of Use, manufacturer, distributor (if applicable), artwork code, symbols required for safe use, transport symbols, storage symbols

	
Printed paper box	The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit. Material: Printed cardboard   Contents of one sales package: 50 pcs
Label for the paper box	Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number Material: Polyester 
UDI Label for the Paper Box	Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code Material: Paper + adhesive 
Group Packag-	The group packaging carton together with the corresponding group packaging label con-

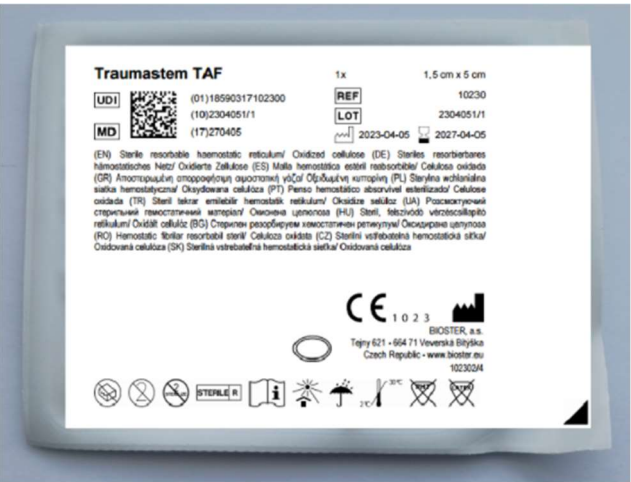
ing Carton	stitutes the group packaging unit containing a predefined number of sales units. Material: Corrugated paper 
Group Packag- ing Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols storage symbols Material : paper + adhesive 
Transport car- ton Transparent ad- hesive sealing tape Stretch film Polypropylene strapping Bubble wrap Paper void fill	Material: Corrugated paper  
Transport carton label	Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols Material: Paper + adhesive

	 Traumacel NEW Dent 1000 x 1 cm x 1,5 cm REF 10115 LOT 2304051/1 2027-04-05 (CZ) Sterilní hemostatická vsťřebatelná kostka pro stomatologii/ Oxidovaná celulóza (SK) Sterilná hemostatická vsťrebateľná kocka pre stomatológiu/ Oxidovaná celulóza CE 1023 BIOSTER, a.s. Tějny 621 - 664 71 Veverská Bítýška Czech Republic - www.bioster.eu 101151014 STERILE R 2°C 30°C
Round blue label Round green label	The labels provide visual identification of the product/package release status. They are placed on the Group packaging box. Material: Paper + adhesive 

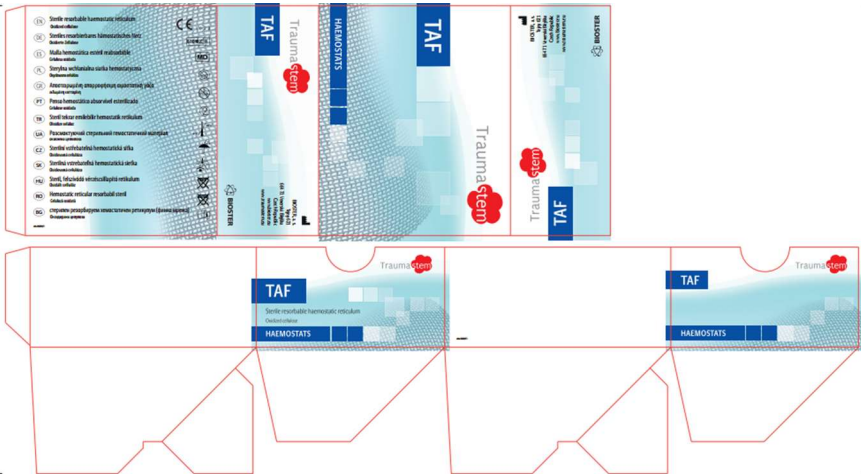
3.7 Traumastem TAF

Primary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed primary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of Use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols 
Secondary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed tertiary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of use, manufacturer, artwork code, sym-

bolts required for safe use, transport symbols, storage symbols, composition.

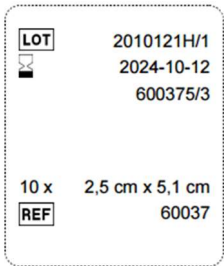


The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit.
Material: Printed cardboard



Contents of one sales package: 10 pcs

Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number
Material: Polyester



Each paper carton additionally carries a UDI label containing:
UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers,

batch number, expiry date, artwork code
Material: Paper + adhesive



Group Packag- ing Carton

The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units.

Material: Corrugated paper



Group Packag- ing Label

The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols

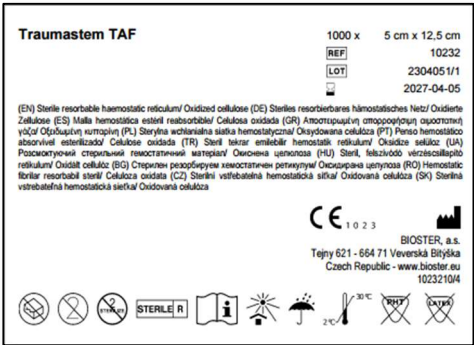
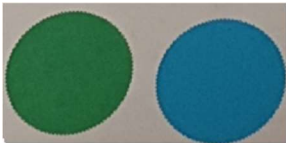
storage symbols
Material : paper + adhesive



**Transport car-
ton**
**Transparent ad-
hesive sealing
tape**
Stretch film
**Polypropylene
strapping**
Bubble wrap
Paper void fill

Material: Corrugated paper



Transport carton label	Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols Material: Paper + adhesive 
Round blue label Round green label	The labels provide visual identification of the product/package release status. They are placed on the Group packaging box. Material: Paper + adhesive 

3.8 Traumastem TAF Light

Primary packaging	Sterile pouch Packaging material -Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed primary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of Use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols
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Sterile pouch

Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA

Material composition: PA/PE 3090 (polyamide, polyethylene)

MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1

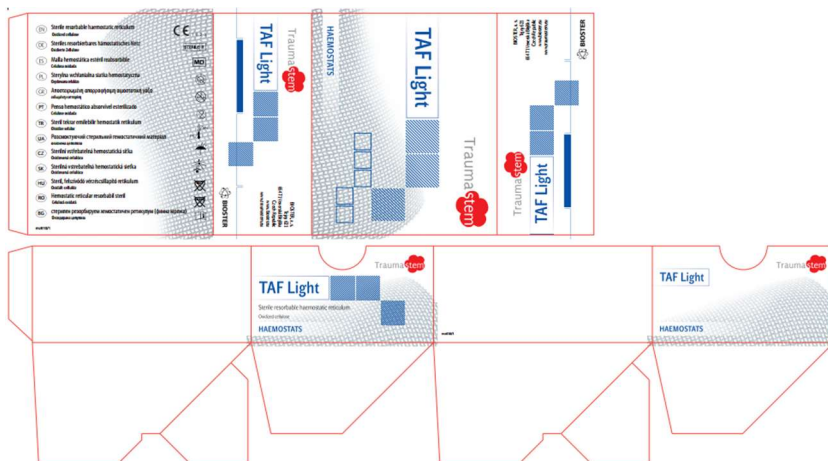
The printed tertiary package includes: REF number, product name, product size
batch number (LOT), expiry date UDI – Unit of use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols, composition.



Secondary packaging

The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit.

Material: Printed cardboard

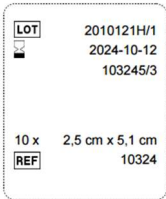
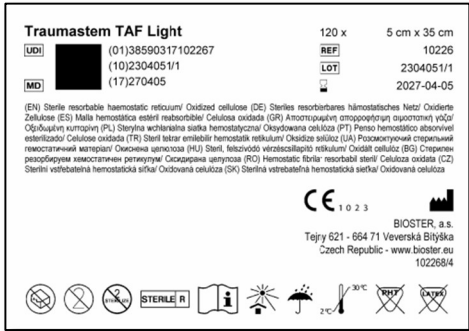


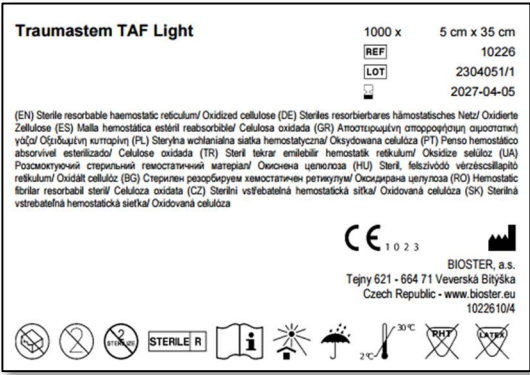
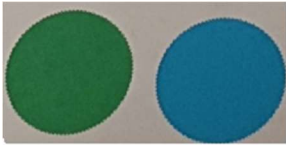
Contents of one sales package: 10 pcs

Printed paper box

Label for the paper box

Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number

	Material: Polyester 
UDI Label for the Paper Box	Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code Material: Paper + adhesive 
Group Packaging Carton	The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units. Material: Corrugated paper 
Group Packaging Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols Material : paper + adhesive 

Transport carton Transparent adhesive sealing tape Stretch film Polypropylene strapping Bubble wrap Paper void fill	Material: Corrugated paper  
Transport carton label	Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols Material: Paper + adhesive 
Round blue label Round green label	The labels provide visual identification of the product/package release status. They are placed on the Group packaging box. Material: Paper + adhesive 

3.9 Traumastem FAM Strata

Primary packaging	Sterile pouch Packaging material -Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed primary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of Use, manufacturer, artwork code, sym-
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bols required for safe use, transport symbols, storage symbols



Sterile pouch

Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA

Material composition: PA/PE 3090 (polyamide, polyethylene)

MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1

The printed tertiary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols, composition.



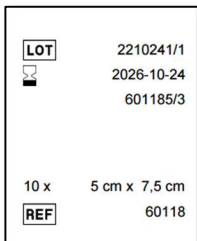
Secondary packaging

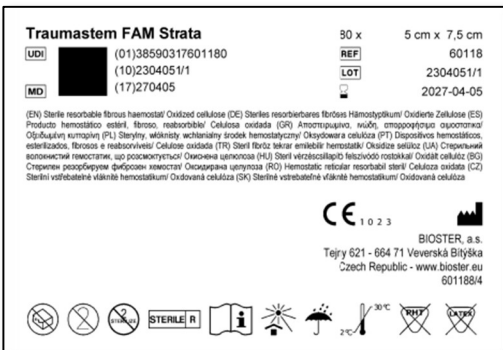
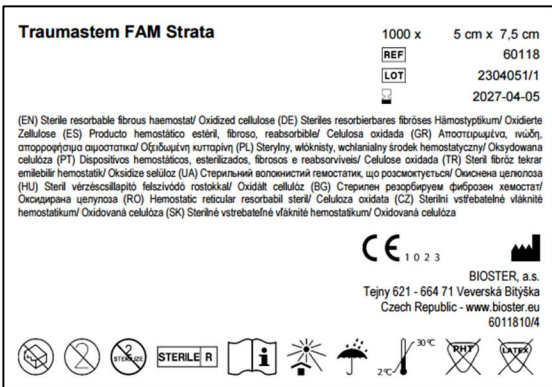
The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit.

Material: Printed cardboard



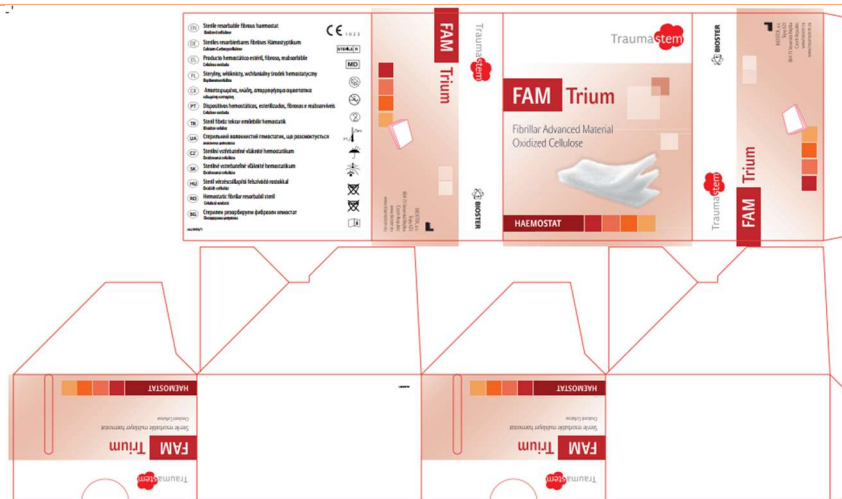
Printed paper box

	Contents of one sales package: 10 pcs
Label for the paper box	Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number Material: Polyester 
UDI Label for the Paper Box	Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code Material: Paper + adhesive 
Group Packaging Carton	The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units. Material: Corrugated paper 
Group Packaging Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols storage symbols Material : paper + adhesive

	
Transport carton Transparent adhesive sealing tape Stretch film Polypropylene strapping Bubble wrap Paper void fill	Material: Corrugated paper  
Transport carton label	Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols Material: Paper + adhesive 
Round blue label Round green label	The labels provide visual identification of the product/package release status. They are placed on the Group packaging box. Material: Paper + adhesive 

3.10 Traumastem FAM Trium

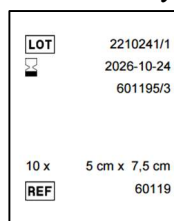
Primary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed primary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of Use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols 
Secondary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed tertiary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols, composition. 
Printed paper box	The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit. Material: Printed cardboard



Contents of one sales package: 10 pcs

Label for the paper box

Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number
Material: Polyester



UDI Label for the Paper Box

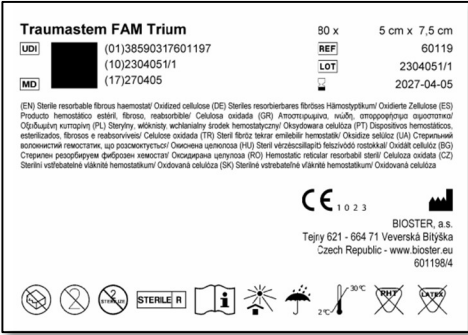
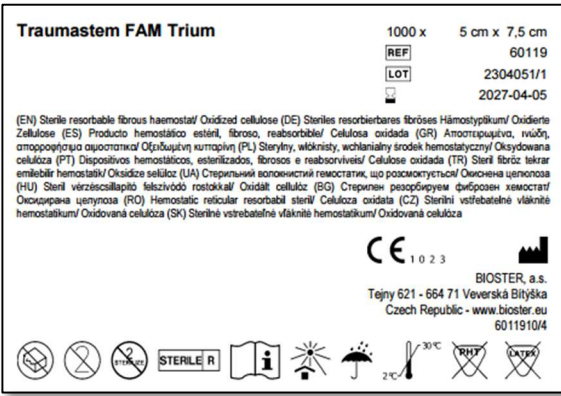
Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code
Material: Paper + adhesive



Group Packaging Carton

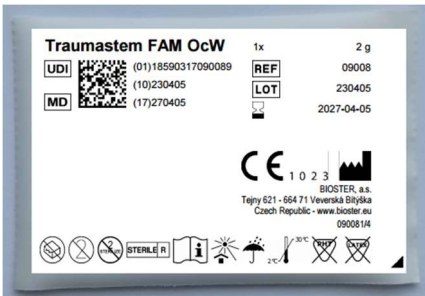
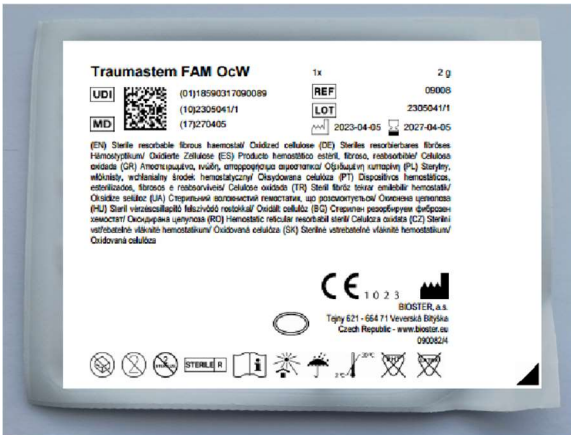
The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units.
Material: Corrugated paper

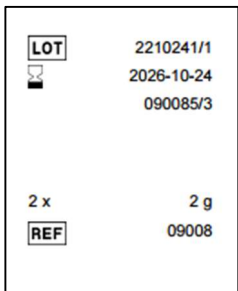


Group Packaging Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols storage symbols Material : paper + adhesive 
Transport carton Transparent adhesive sealing tape Stretch film Polypropylene strapping Bubble wrap Paper void fill	Material: Corrugated paper  
Transport carton label	Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols Material: Paper + adhesive 
Round blue label Round green label	The labels provide visual identification of the product/package release status. They are placed on the Group packaging box. Material: Paper + adhesive

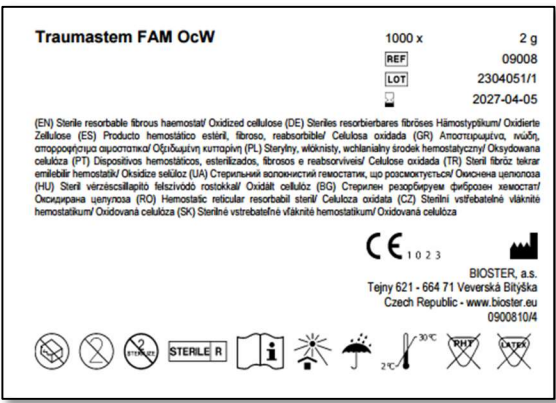
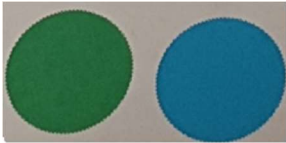


3.11 Traumastem FAM OcW

Primary packaging	Sterile pouch Packaging material -Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed primary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of Use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols 
Secondary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 The printed tertiary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of use, manufacturer, artwork code, symbols required for safe use, transport symbols, storage symbols, composition. 
Printed paper box	The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit. Material: Printed cardboard

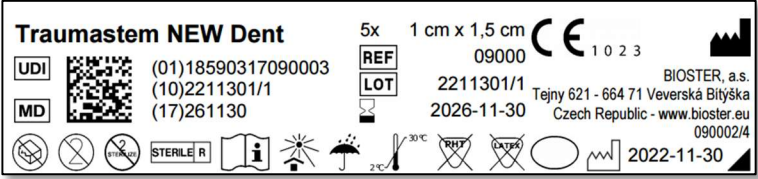
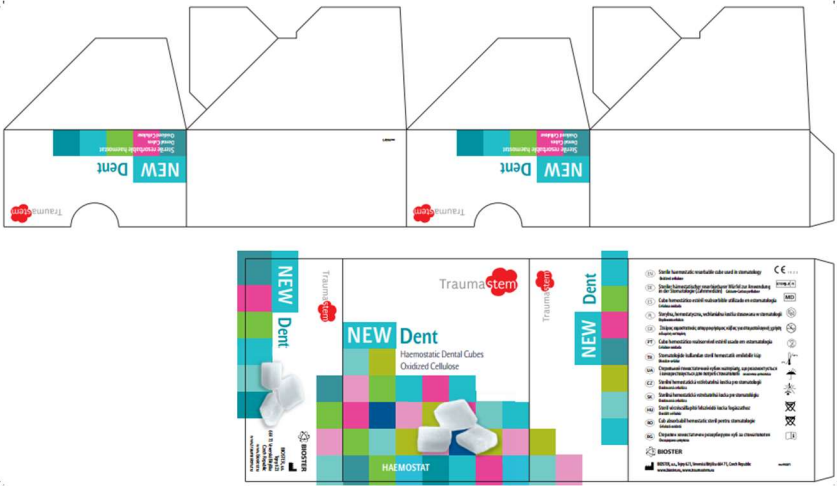
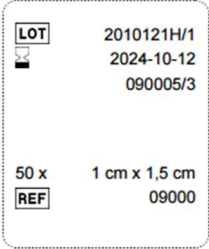
	 Contents of one sales package: 10 pcs
Label for the paper box	Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number Material: Polyester 
UDI Label for the Paper Box	Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code Material: Paper + adhesive 
Group Packaging Carton	The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units. Material: Corrugated paper

	
Group Packaging Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols storage symbols Material : paper + adhesive 
Transport carton Transparent adhesive sealing tape Stretch film Polypropylene strapping Bubble wrap Paper void fill	Material: Corrugated paper  
Transport carton label	Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols Material: Paper + adhesive

	
Round blue label Round green label	The labels provide visual identification of the product/package release status. They are placed on the Group packaging box. Material: Paper + adhesive 

3.12 Traumastem NEW Dent

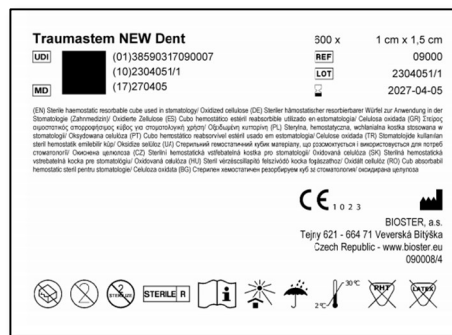
Primary packaging	Sterile pouch Packaging material - Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA Material composition: PA/PE 3090 (polyamide, polyethylene) MEDIFLEX Type ARHA - Medical-grade paper, adhesive layer, Rayopeel Y/R1 
Label for primary packaging	The label contains: REF number, product name, product size, batch number (LOT), expiry date UDI – Unit of Use, manufacturer, distributor (if applicable), artwork code, symbols required for safe use, transport symbols, storage symbols

	 Traumastem NEW Dent 5x 1 cm x 1,5 cm REF 09000 LOT 2211301/1 2026-11-30 BIOSTER, a.s. Tejny 621 - 664 71 Veverská Bítýška Czech Republic - www.bioster.eu 090002/4 2022-11-30
Printed paper box	The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper box represents the sales unit. Material: Printed cardboard  Contents of one sales package: 50 pcs
Label for the paper box	Each paper box carries a label including: Batch number, expiry date, artwork code, quantity per box, REF number Material: Polyester 
UDI Label for the Paper Box	Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code Material: Paper + adhesive 
Group Packaging Carton	The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units. Material: Corrugated paper



Group Packaging Label

The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, artwork code, symbols for safe use, transport symbols
storage symbols
Material : paper + adhesive



Transport carton
Transparent adhesive sealing tape
Stretch film
Polypropylene strapping
Bubble wrap
Paper void fill

Material: Corrugated paper



Transport carton label

Where shipment requires an additional transport carton, the appropriate transport label shall be applied. The label contains: REF number, product name, product size, batch number, expiry date, product description, manufacturer, artwork code, symbols for safe handling, transport symbols, storage symbols
Material: Paper + adhesive

Round blue label Round green label	The labels provide visual identification of the product/package release status. They are placed on the Group packaging box. Material: Paper + adhesive

4. Material Composition

4.1 Materials Used

Name of the packaging	Packaging description	Composition	Producer
Primary packaging	Vacuum packaging film	PA/PE 3090: polyamid, polyethylen	Vepak, s.r.o.
		MEDIFLEX typ ARHA: papír, adhesivum, Rayopeel Y/R1	Ancor
Secondary packaging	Vacuum packaging film	PA/PE 3090: polyamid, polyethylen	Vepak, s.r.o.
		MEDIFLEX typ ARHA: papír, adhesivum, Rayopeel Y/R1	Ancor

Label for primary packaging	Self-adhesive label	Paper + adhesive	Rayfilm s.r.o.
Thermal transfer ribbon	Printing consumable used to print variable information on labels or packaging.	Polyester, resin, paraffin wax, carnauba wax, carbon black, polyethylene terephthalate PETP	TFP Universal a.s.
Paper box	Printed folded carton	Printed paper	Polygra, a.s.
Label for paper box	Self-adhesive label	Polyester	Rayfilm s.r.o.
Label for paper box with UDI	Self-adhesive label.	Paper + adhesive	Rayfilm s.r.o.
Group packaging carton	Corrugated transport carton	Corrugated paper	Probas, s.r.o.
Label for group packaging carton	Self-adhesive label	Paper + adhesive	Rayfilm s.r.o.
Transport carton	Corrugated transport carton	Corrugated paper	Probas, s.r.o.
Label for transport carton	Self-adhesive label	Paper + adhesive	Rayfilm s.r.o.
Package leaflet / instructions for use	Provides user information, instructions for use, warnings and precautions.	Printed paper	Polygra, a.s.
Transparent adhesive sealing tape	Seals outer cartons for storage, handling and transport.	Polypropylene	Europapier
Round blue label	Indicates finished batch	Paper + adhesive	Rayfilm s.r.o.
Round green label	Indicates released batch	Paper + adhesive	Rayfilm s.r.o.
Stretch film	Protects carton boxes during transport.	LDPE	Europapier
Polypropylene strapping	Holds carton boxes during transport on wooden pallet	Polypropylene	Europapier
Bubble wrap	Cushions products and protects them against impact and movement.	LDPE	Europapier

Paper void fill	Fills empty space and prevents product movement inside the box.	paper	Europapier
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Material specifications and supplier certificates are included in the Annexes.

4.2 Packaging Configuration

4.2.1 Traumacel TAF (all sizes)

Traumacel TAF Light (all sizes)

Name of the packaging	Weight of the packaging (g)	Weight per 1 pc (g)	Weight share (%)	Share of recycled material (%)
Primary packaging	1,6	1,60	13,20	0
Secondary packaging	3,8	3,80	31,35	0
Thermal transfer ribbon	variable	variable	N/A	0
Paper box	39	3,90	32,17	0
Label for paper box	0,1	0,01	0,08	0
Label for paper box with UDI	0,1	0,01	0,08	0
Group packaging carton	165	1,38	11,38	70
Label for group packaging carton	1,3	0,01	0,08	0
Transport carton	809	1,12	9,24	70
Label for transport carton	1,3	0,002	0,02	0
Package leaflet / instructions for use	2,9	0,29	2,39	0
Transparent adhesive sealing tape	variable	variable	N/A	0

Round blue label	0,01	0	0,00	0
Round green label	0,01	0	0,00	0
Stretch film	variable	variable	N/A	0
Polypropylene strapping	variable	variable	N/A	0
Bubble wrap	variable	variable	N/A	0
Paper void fill	variable	variable	N/A	0

Note: Weight shares are calculated using packaging components with a known, non-zero weight per sales unit. Components reported as “variable” or without a quantified per-unit weight are excluded from the calculation. The included components are normalized to 100%. Therefore, the stated shares represent the known packaging mass rather than the complete packaging system.

4.2.2 Traumacel FAM Strata 2,5 x 5 cm

Traumacel FAM Trium 2,5 x 5 cm

Name of the packaging	Weight of the packaging (g)	Weight per 1 pc (g)	Weight share (%)	Share of recycled material (%)
Primary packaging	1,6	1,60	11,83	0
Secondary packaging	3,8	3,80	28,09	0
Thermal transfer ribbon	variable	variable	N/A	0
Paper box	45	4,50	33,26	0
Label for paper box	0,2	0,02	0,15	0
Label for paper box with UDI	0,1	0,01	0,07	0
Group packaging carton	240	1,50	11,09	70
Label for group packaging carton	1,3	0,01	0,07	0
Transport carton	846	1,76	13,01	70
Label for transport carton	1,3	0,04	0,30	0
Package leaflet / instructions for use	2,9	0,29	2,14	0
Transparent	variable	variable	N/A	0

adhesive sealing tape				
Round blue label	0,01	0	N/A	0
Round green label	0,01	0	N/A	0
Stretch film	0,01	0	N/A	0
Polypropylene strapping	variable	variable	N/A	0
Bubble wrap	variable	variable	N/A	0
Paper void fill	variable	variable	N/A	0

Note: Weight shares are calculated using packaging components with a known, non-zero weight per sales unit. Components reported as “variable” or without a quantified per-unit weight are excluded from the calculation. The included components are normalized to 100%. Therefore, the stated shares represent the known packaging mass rather than the complete packaging system.

4.2.3 Traumacel FAM Strata 5 x 10 cm; 10 x 10 cm; 5 x 7,5 cm Traumacel FAM Trium 5 x 10 cm; 10 x 10 cm; 5 x 7,5 cm

Name of the packaging	Weight of the packaging (g)	Weight per 1 pc (g)	Weight share (%)	Share of recycled material (%)
Primary packaging	4,1	4,10	17,73	0
Secondary packaging	7,6	7,60	32,86	0
Thermal transfer ribbon	variable	variable	N/A	0
Paper box	78	7,80	33,72	0
Label for paper box	0,2	0,02	0,09	0
Label for paper box with UDI	0,1	0,01	0,04	0
Group packaging carton	240	1,50	6,49	70
Label for group packaging carton	1,3	0,01	0,04	0
Transport carton	846	1,76	7,61	70
Label for transport carton	1,3	0,04	0,17	0

Package leaflet / instructions for use	2,9	0,29	1,25	0
Transparent adhesive sealing tape	variable	variable	N/A	0
Round blue label	0,01	0	N/A	0
Round green label	0,01	0	N/A	0
Stretch film	0,01	0	N/A	0
Polypropylene strapping	variable	variable	N/A	0
Bubble wrap	variable	variable	N/A	0
Paper void fill	variable	variable	N/A	0

Note: Weight shares are calculated using packaging components with a known, non-zero weight per sales unit. Components reported as “variable” or without a quantified per-unit weight are excluded from the calculation. The included components are normalized to 100%. Therefore, the stated shares represent the known packaging mass rather than the complete packaging system.

4.2.4 Traumacel FAM OcW

Name of the packaging	Weight of the packaging (g)	Weight per 1 pc (g)	Weight share (%)	Share of recycled material (%)
Primary packaging	1,6	1,60	5,12	0
Secondary packaging	3,8	3,80	12,16	0
Thermal transfer ribbon	variable	variable	N/A	0
Paper box	78	7,80	24,97	0
Label for paper box	0,1	0,05	0,16	0
Label for paper box with UDI	0,1	0,05	0,16	0
Group packaging carton	240	7,5	24,01	70
Label for group packaging carton	1,3	0,04	0,13	0
Transport carton	846	8,81	28,20	70
Label for transport carton	1,3	0,14	0,45	0

Package leaflet / instructions for use	2,9	1,45	4,64	0
Transparent adhesive sealing tape	variable	variable	N/A	0
Round blue label	0,01	0	N/A	0
Round green label	0,01	0	N/A	0
Stretch film	0,01	0	N/A	0
Polypropylene strapping	variable	variable	N/A	0
Bubble wrap	variable	variable	N/A	0
Paper void fill	variable	variable	N/A	0

Note: Weight shares are calculated using packaging components with a known, non-zero weight per sales unit. Components reported as “variable” or without a quantified per-unit weight are excluded from the calculation. The included components are normalized to 100%. Therefore, the stated shares represent the known packaging mass rather than the complete packaging system.

4.2.5 Traumacel NEW Dent

Name of the packaging	Weight of the packaging (g)	Weight per 1 pc (g)	Weight share (%)	Share of recycled material (%)
Primary packaging	1,3	0,26	15,29	0
Secondary packaging	N/A	N/A	N/A	0
Label for primary packaging	0,2	0,04	2,35	
Thermal transfer ribbon	variable	variable	N/A	0
Paper box	45	0,9	52,94	0
Label for paper box	0,2	0,00	N/A	0
Label for paper box with UDI	0,1	0,00	N/A	0
Group packaging carton	165	0,22	12,94	70
Label for group packaging carton	1,3	0,00	N/A	0
Transport carton	809	0,22	12,94	70

Label for transport carton	1,3	0,00	N/A	0
Package leaflet / instructions for use	2,9	0,06	3,53	0
Transparent adhesive sealing tape	variable	variable	N/A	0
Round blue label	0,01	0	N/A	0
Round green label	0,01	0	N/A	0
Stretch film	0,01	0	N/A	0
Polypropylene strapping	variable	variable	N/A	0
Bubble wrap	variable	variable	N/A	0
Paper void fill	variable	variable	N/A	0

Note: Weight shares are calculated using packaging components with a known, non-zero weight per sales unit. Components reported as “variable” or without a quantified per-unit weight are excluded from the calculation. The included components are normalized to 100%. Therefore, the stated shares represent the known packaging mass rather than the complete packaging system.

4.2.6 Traumastem TAF (all sizes)

Traumastem TAF Light (all sizes)

Name of the packaging	Weight of the packaging (g)	Weight per 1 pc (g)	Weight share (%)	Share of recycled material (%)
Primary packaging	1,6	1,60	12,30	0
Secondary packaging	3,8	3,80	29,22	0
Thermal transfer ribbon	variable	variable	N/A	0
Paper box	39	3,90	29,99	0
Label for paper box	0,1	0,01	0,08	0
Label for paper box with UDI	0,1	0,01	0,08	0
Group packaging carton	165	1,38	10,61	70
Label for group	1,3	0,01	0,08	0

packaging carton				
Transport carton	809	1,12	8,61	70
Label for transport carton	1,3	0,002	0,02	0
Package leaflet / instructions for use	11,7	1,17	9,00	0
Transparent adhesive sealing tape	variable	variable	N/A	0
Round blue label	0,01	0	N/A	0
Round green label	0,01	0	N/A	0
Stretch film	variable	variable	N/A	0
Polypropylene strapping	variable	variable	N/A	0
Bubble wrap	variable	variable	N/A	0
Paper void fill	variable	variable	N/A	0

Note: Weight shares are calculated using packaging components with a known, non-zero weight per sales unit. Components reported as “variable” or without a quantified per-unit weight are excluded from the calculation. The included components are normalized to 100%. Therefore, the stated shares represent the known packaging mass rather than the complete packaging system.

4.2.7 Traumastem FAM Strata 2,5 x 5 cm

Traumastem FAM Trium 2,5 x 5 cm

Name of the packaging	Weight of the packaging (g)	Weight per 1 pc (g)	Weight share (%)	Share of recycled material (%)
Primary packaging	1,6	1,60	11,10	0
Secondary packaging	3,8	3,80	26,37	0
Thermal transfer ribbon	variable	variable	N/A	0
Paper box	45	4,50	31,23	0
Label for paper box	0,2	0,02	0,14	0
Label for paper box with UDI	0,1	0,01	0,07	0

Group packaging carton	240	1,50	10,41	70
Label for group packaging carton	1,3	0,01	0,07	0
Transport carton	846	1,76	12,21	70
Label for transport carton	1,3	0,04	0,28	0
Package leaflet / instructions for use	11,7	1,17	8,12	0
Transparent adhesive sealing tape	variable	variable	N/A	0
Round blue label	0,01	0	N/A	0
Round green label	0,01	0	N/A	0
Stretch film	0,01	0	N/A	0
Polypropylene strapping	variable	variable	N/A	0
Bubble wrap	variable	variable	N/A	0
Paper void fill	variable	variable	N/A	0

Note: Weight shares are calculated using packaging components with a known, non-zero weight per sales unit. Components reported as “variable” or without a quantified per-unit weight are excluded from the calculation. The included components are normalized to 100%. Therefore, the stated shares represent the known packaging mass rather than the complete packaging system.

4.2.8 Traumastem FAM Strata 5 x 10 cm; 10 x 10 cm; 5 x 7,5 cm

Traumastem FAM Trium 5 x 10 cm; 10 x 10 cm; 5 x 7,5 cm

Name of the packaging	Weight of the packaging (g)	Weight per 1 pc (g)	Weight share (%)	Share of recycled material (%)
Primary packaging	4,1	4,10	17,08	0
Secondary packaging	7,6	7,60	31,65	0
Thermal transfer ribbon	variable	variable	N/A	0
Paper box	78	7,80	32,49	0

Label for paper box	0,2	0,02	0,08	0
Label for paper box with UDI	0,1	0,01	0,04	0
Group packaging carton	240	1,50	6,25	70
Label for group packaging carton	1,3	0,01	0,04	0
Transport carton	846	1,76	7,33	70
Label for transport carton	1,3	0,04	0,17	0
Package leaflet / instructions for use	11,7	1,17	4,87	0
Transparent adhesive sealing tape	variable	variable	N/A	0
Round blue label	0,01	0	N/A	0
Round green label	0,01	0	N/A	0
Stretch film	0,01	0	N/A	0
Polypropylene strapping	variable	variable	N/A	0
Bubble wrap	variable	variable	N/A	0
Paper void fill	variable	variable	N/A	0

Note: Weight shares are calculated using packaging components with a known, non-zero weight per sales unit. Components reported as “variable” or without a quantified per-unit weight are excluded from the calculation. The included components are normalized to 100%. Therefore, the stated shares represent the known packaging mass rather than the complete packaging system.

4.2.9 Traumacel FAM OcW

Name of the packaging	Weight of the packaging (g)	Weight per 1 pc (g)	Weight share (%)	Share of recycled material (%)
Primary packaging	1,6	1,60	4,49	0
Secondary packaging	3,8	3,80	10,66	0
Thermal transfer ribbon	variable	variable	N/A	0
Paper box	78	7,80	21,89	0

Label for paper box	0,1	0,05	0,14	0
Label for paper box with UDI	0,1	0,05	0,14	0
Group packaging carton	240	7,5	21,04	70
Label for group packaging carton	1,3	0,04	0,11	0
Transport carton	846	8,81	24,72	70
Label for transport carton	1,3	0,14	0,39	0
Package leaflet / instructions for use	11,7	5,85	16,41	0
Transparent adhesive sealing tape	variable	variable	N/A	0
Round blue label	0,01	0	N/A	0
Round green label	0,01	0	N/A	0
Stretch film	0,01	0	N/A	0
Polypropylene strapping	variable	variable	N/A	0
Bubble wrap	variable	variable	N/A	0
Paper void fill	variable	variable	N/A	0

Note: Weight shares are calculated using packaging components with a known, non-zero weight per sales unit. Components reported as “variable” or without a quantified per-unit weight are excluded from the calculation. The included components are normalized to 100%. Therefore, the stated shares represent the known packaging mass rather than the complete packaging system.

4.2.10 Traumastem NEW Dent

Name of the packaging	Weight of the packaging (g)	Weight per 1 pc (g)	Weight share (%)	Share of recycled material (%)
Primary packaging	1,3	0,26	13,87	0
Secondary packaging	N/A	N/A	N/A	0
Label for primary packaging	0,2	0,04	2,13	
Thermal transfer	variable	variable	N/A	0

ribbon				
Paper box	45	0,9	48,03	0
Label for paper box	0,2	0,00	N/A	0
Label for paper box with UDI	0,1	0,00	N/A	0
Group packaging carton	165	0,22	11,74	70
Label for group packaging carton	1,3	0,00	N/A	0
Transport carton	809	0,22	12,49	70
Label for transport carton	1,3	0,00	N/A	0
Package leaflet / instructions for use	77,7	0,234		0
Transparent adhesive sealing tape	variable	variable	N/A	0
Round blue label	0,01	0	N/A	0
Round green label	0,01	0	N/A	0
Stretch film	0,01	0	N/A	0
Polypropylene strapping	variable	variable	N/A	0
Bubble wrap	variable	variable	N/A	0
Paper void fill	variable	variable	N/A	0

Note: Weight shares are calculated using packaging components with a known, non-zero weight per sales unit. Components reported as “variable” or without a quantified per-unit weight are excluded from the calculation. The included components are normalized to 100%. Therefore, the stated shares represent the known packaging mass rather than the complete packaging system.

4.3 Substances of Concern

The content and concentration of substances of concern, as defined in Article 2(27) of Regulation (EU) 2024/1781, in the packaging material and in the individual packaging components comply with the requirements of Regulation (EC) No 1907/2006 (REACH), and statements regarding their content in the packaging components form part of the annex documentation containing the specification sheets provided by the suppliers of the packaging materials.

All packaging components comply with the limits laid down in the PPWR for the content of lead, cadmium, mercury, hexavalent chromium and PFAS.

5. Manufacturing Information

5.1 Manufacturing Process

The machine operator selects the appropriate print layout from the machine memory, installs the forming dies, sealing dies and depth-adjustment inserts, and starts the machine.

The oxidized cellulose blanks are fed into the packaging machine, where they are packed into **Primary packaging**. The packaged products are discharged from the packaging machine outlet, inspected and placed in crates. For Traumastem NEW Dent and Traumacel NEW Dent, the primary packaging is labelled with the **Label for primary packaging**.

For the secondary packaging process, the machine operator selects the secondary packaging print layout from the machine memory, installs the forming dies, sealing dies and depth-adjustment inserts, and starts the machine. The operators feed the product already packed in the primary packaging into the packaging machine, where they are packed in the **Secondary packaging**. The primary and secondary packaging, as well as the applicable labels, are printed using the **Thermal transfer ribbon**, which is used as a printing consumable.

The products packed in primary and secondary packaging are placed in the **Paper boxes**, in the quantities specified for each product in Chapter 3, together with the **Package leaflet / Instructions for use**. The paper boxes are then labelled with the **Label for paper box** and **Label for paper box with UDI**.

The paper boxes are packed in the **Group packaging cartons**, which are labelled with the **Label for group packaging carton**, the **Round blue label** and the **Round green label**.

The group packaging cartons are placed in the **Transport cartons**. The transport cartons are labelled with the **Label for transport carton**, sealed with **Transparent adhesive sealing tape** and stacked in several layers on EUR or standard pallets. If a transport carton is not completely filled, the empty space is filled with cushioning material, either **Bubble wrap** or **Paper void fill**. The transport cartons are secured to the pallet using **Stretch film** and **Polypropylene strapping**.

5.2 Production Control

The operators inspect the products packed in primary and secondary packaging at the output of the packaging machine. If a defective package is identified, the product is placed into a designated container.

The operators visually inspect: the print quality, the cleanliness of the packaging material, whether the product has been sealed into the package seal.

Defectively packaged products are unpacked and inspected.

Products that pass the inspection are repackaged using the same procedure described above.

Products that cannot be reused are placed into a closed and identified container. Products collected in this manner are subsequently disposed of.

6. Compliance with PPWR Requirements

6.1 Overview of Relevant Requirements

Area	Requirement	Exemption for Medical Devices	Relevance to the Packaging	Demonstration of Compliance
Substances in packaging	Minimise substances of concern; the combined concentration of Pb, Cd, Hg and Cr(VI) shall not exceed 100 mg/kg. PFAS limits apply to food-contact packaging.	Packaging of medical devices not intended for food contact is not subject to the specific PFAS prohibition under Article 5(5) PPWR.	Yes	The annexes to the technical documentation contain material specifications and supplier documents declaring compliance with the limits for substances of concern.
Recyclability	All packaging shall be recyclable and shall progressively achieve the required recyclability performance grades.	Does not apply to contact-sensitive packaging used for medical devices under the MDR or IVDs under the IVDR (Article 6(11)(b),(c)).	No	—
Recycled content in plastic	Plastic packaging shall contain the prescribed proportion of post-consumer recycled plastic. From 2030, depending on the category, this ranges from 10–35%; from 2040, from 25–65%.	Does not apply to contact-sensitive plastic packaging used for MDR medical devices, including devices intended exclusively for investigation and clinical investigation devices, nor to IVDs (Article 7(4)(b),(c)).	Yes, for group and transport packaging	Applicable from 1 January 2030
Compostability	Tea bags, coffee pods and similar applications, and adhesive labels attached to fruit and vegetables, shall be industrially compostable. Other bi-	—	No	—

	odegradable packaging should generally remain materially recyclable.			
Minimisation	Packaging weight and volume shall be reduced to the minimum necessary for its functionality. False bottoms, double walls and unnecessary layers creating the impression of a larger product are prohibited.	—	Yes	Applicable from 1 January 2030
Reusable packaging	Packaging shall be designed for multiple cycles, be safely emptyable, refillable or reusable, reconditionable and recyclable at the end of its life.	—	No	—
Restricted packaging formats	Certain single-use packaging formats are prohibited, for example selected plastic group packaging, packaging for fresh fruit and vegetables up to 1.5 kg, single-use packaging for on-site consumption in the HORECA sector, and hotel miniature cosmetic packaging.	—	No	Applicable from 1 January 2030
Harmonised labelling	Article 12 does not apply to the immediate and outer packaging of MDR/IVDR devices where no space remains due to mandatory	—	Yes	The packaging bears the address of the packaging manufacturer.

	MDR/IVDR labeling requirements (Article 12(11)).			
Conformity assessment and retention of documentation	Custom-made transport packaging for configurable medical devices and systems intended for industrial and healthcare facilities is exempt from conformity assessment, technical documentation/EU declaration and document retention requirements under Article 15(2) and (3). This exemption does not apply to the substantive packaging requirements (Article 15(11)).	—	Yes	All products are supplied in single-use packaging. Documentation is retained for five years.

6.2 Environmental Claims

No environmental claims are used on the packaging.

7 Standards and Specifications Applied

7.1 Harmonised Standards

As of the date of preparation of this technical documentation, no harmonised standards relevant to the requirements of **Regulation (EU) 2025/40 (PPWR)** with references published in the **Official Journal of the European Union** have been applied.

Compliance of the packaging with the applicable requirements of the Regulation has been assessed on the basis of technical specifications. The corresponding test reports and calculations are included in the annexes to this technical documentation.

7.2 Common Specifications

As of the date of preparation of this technical documentation, no **Common Specifications (CS)** issued pursuant to **Article 37 of Regulation (EU) 2025/40 (PPWR)** have been published or applied to the packaging under assessment.

Compliance of the packaging with the applicable requirements of the Regulation has been assessed on the basis of technical specifications. The corresponding test reports and calculations are included in the annexes to this technical documentation.

7.3 Other Technical Specifications

The annexes to this technical documentation contain material specification sheets and supporting documents relating to the individual packaging materials used.

8 Risk Assessment

8.1 Risk Assessment Method

Probability of Occurrence

Value	Description
1	Low – non-compliance is unlikely and is effectively controlled.
2	Medium – non-compliance may occur due to a change in material, supplier or design.
3	High – the requirement is not documented or the current design is likely not to comply with the requirement.

Severity of Consequences

Value	Description
1	Low – administrative or documentation deficiency without a direct impact on safety.
2	Medium – corrective action, modification of the documentation or packaging is required.
3	High – prohibition of placing the packaging on the market, product recall, regulatory action, or a potential impact on the safety of the medical device.

Risk Classification

The Risk Priority Number (R) is determined as follows:

R = Probability × Severity

Result	Risk Classification
1–2	Low risk
3–4	Medium risk
6–9	High risk

8.2 Identification of Risks of Non-compliance

The following PPWR requirements have been identified as relevant for the assessment of packaging compliance:

- **Substances contained in packaging** – Article 5 PPWR
- **Recyclability** – Article 6 PPWR
- **Minimum recycled plastic content** – Article 7 PPWR
- **Compostability** – Article 9 PPWR
- **Minimisation of packaging weight and volume** – Article 10 and Annex IV PPWR
- **Reusable packaging** – Articles 11, 26 and 29 PPWR
- **Packaging labelling** – Article 12 PPWR
- **Excessive empty space** – Article 24 PPWR

8.3 Risk Evaluation Including Risk Control Measures

8.3.1 Substances Contained in Packaging – Article 5 PPWR

Identified Hazard

The packaging or its components may contain: lead; cadmium; mercury; hexavalent chromium; other substances of concern; PFAS in materials, coatings, barrier layers, printing inks, adhesives or processing aids.

The combined concentration of Pb, Cd, Hg and Cr(VI) in the packaging or its components shall not exceed 100 mg/kg, unless a specific exemption applies.

The PFAS limits under Article 5(5) apply to food-contact packaging. This specific requirement does not generally apply to packaging for medical devices. However, the general obligation to minimise substances of concern remains applicable.

Risk Assessment

Packaging under assessment	Relevance	P	S	R	Evaluation
Sterile barrier system – primary, secondary and tertiary packaging	Yes	2	3	6	High before implementation of control measures
Paper carton	Yes	2	2	4	Medium
Group and transport packaging	Yes	1	2	2	Low
PFAS limit applicable to food-contact packaging	No, where the packaging is not intended for food contact	1	1	1	Specific limit not applicable

Evidence for Verification

- material specifications for all packaging layers;
- complete composition of laminates and barrier layers;
- supplier declarations regarding Pb, Cd, Hg and Cr(VI) content;
- declarations of compliance with REACH and the Regulation on Persistent Organic Pollutants;
- declarations confirming the presence or absence of PFAS;
- safety data sheets for adhesives, inks, coatings and processing aids;
- laboratory analysis where supplier declarations are insufficient or increased risk has been identified;
- change control system covering suppliers, materials, formulations, adhesives, inks and surface treatments.

Risk Control Measures

A written declaration is required from each packaging material supplier confirming that the combined concentration of Pb, Cd, Hg and Cr(VI) does not exceed 100 mg/kg.

Current material specifications and declarations regarding chemical composition are maintained for each material.

Suppliers shall notify any change to formulations, layers, pigments, printing inks, adhesives or surface treatments before implementation.

For multilayer packaging, each individual layer and component is assessed separately rather than only the finished laminate.

Where the composition is not adequately documented, laboratory testing shall be performed using an

appropriate analytical method.

PFAS are monitored as part of the chemical characterisation and management of substances of concern, even though the specific limits under Article 5(5) are not directly applicable to medical device packaging.

Residual Risk

P = 1, S = 3, R = 3 – Medium, acceptable provided that supplier documentation is regularly updated and change control procedures are maintained.

8.3.2 Recyclability – Article 6 PPWR

Identified Hazard

The combination of materials, barrier layers, surface treatments, adhesives or the packaging design may prevent or significantly limit:

- identification of the material during sorting;
- separation of individual layers;
- allocation to an existing recycling stream;
- recovery of secondary raw materials of adequate quality;
- large-scale recycling of the packaging.

Applicability of the Exemption for Medical Devices

Article 6 does not apply to contact-sensitive packaging of medical devices under Regulation (EU) 2017/745. The exemption therefore applies to packaging that is in contact with the medical device or whose properties are essential for maintaining the protection, sterility or safety of the device.

This typically includes:

the sterile barrier system – primary, secondary and tertiary packaging, comprising the layers necessary to maintain sterility and the safety of the medical device.

The exemption does not automatically apply to group or transport packaging. For the secondary sales carton, it must be individually demonstrated whether it forms part of the contact-sensitive packaging system or is merely a conventional outer sales package.

Risk Assessment

Packaging under assessment	Relevance	P	S	R	Evaluation
Sterile barrier system – primary, secondary and tertiary packaging	Requirement of Article 6 exempt pursuant to Article 6(11)(b)	1	3	3	Medium – risk of incorrect application of the exemption
Paper carton	Yes	1	2	2	Low
Group packaging	Yes	1	2	2	Low
Transport packaging	Yes	1	2	2	Low

Evidence for Verification

For the sterile barrier system:

- description of the function of each packaging layer;
- justification for classification as contact-sensitive packaging;
- sterile barrier system documentation.

- For all other packaging:
- detailed material composition;
- mass fraction of individual materials;
- identification of integrated and separable components;
- assessment of compatibility with sorting and recycling processes;
- supplier declaration regarding recyclability;
- recyclability test reports, where available;
- assessment of the effects of labels, adhesives, printing inks, varnishes, coatings and barrier layers.

Risk Control Measures

The sterile barrier system is clearly identified in the technical documentation as contact-sensitive packaging for a medical device.

It is documented that the multilayer construction is necessary to ensure:

- maintenance of the sterile barrier;
- mechanical protection;
- the required permeability to the sterilising agent;
- protection against moisture and oxygen;
- seal strength;
- microbial barrier performance;
- aseptic opening;
- maintenance of performance after sterilisation and throughout the declared shelf life.

The legal basis for the exemption is documented as Article 6(11)(b) PPWR.

Secondary, group and transport packaging are designed, wherever possible, as monomaterial structures or easily separable material combinations.

Only labels, adhesives, varnishes and printing inks that do not significantly impair recyclability are used on paper and paperboard packaging.

Recyclability is reassessed whenever there is a change in material, packaging design, label, adhesive, coating or supplier.

Justification for Non-applicability to the Sterile Barrier System

"Article 6 PPWR is not applicable to the sterile barrier system of the medical device pursuant to the exemption provided in Article 6(11)(b), as it constitutes contact-sensitive packaging for a medical device within the meaning of Regulation (EU) 2017/745. The multilayer construction is essential for maintaining the sterile barrier, packaging integrity, medical device safety and aseptic presentation."

Residual Risk

P = 1, S = 3, R = 3 – Medium, acceptable provided that the scope of the exemption is properly justified for the specific packaging configuration.

8.3.3 Minimum Recycled Plastic Content – Article 7 PPWR

Identified Hazard

Plastic packaging may fail to contain the prescribed minimum proportion of recycled plastic.

Applicability of the Exemption

Under Article 7(4)(b) PPWR, the minimum recycled-content requirements do not apply to contact-sensitive plastic packaging of medical devices covered by Regulation (EU) 2017/745.

Risk Assessment

Packaging under assessment	Relevance	P	S	R	Evaluation
Sterile barrier system – primary, secondary and tertiary packaging	Exemption pursuant to Article 7(4)(b)	1	3	3	Medium – risk of incorrect classification
Paper carton	Yes	1	2	2	Medium
Group packaging	Yes	1	2	2	Low
Transport packaging	Yes	1	2	2	Low

Evidence for Verification

supplier declaration regarding material composition;
determination whether the packaging meets the definition of contact-sensitive packaging;
supplier information regarding the proportion of post-consumer recycled content;
calculations and records of recycled content for packaging not covered by the exemption.

Risk Control Measures

The exemption under Article 7(4)(b) is documented for the sterile barrier system.

It is documented that the use of recycled plastic could affect:

- material purity;
- consistency of material properties;
- microbial barrier performance;
- sealability;
- seal strength and integrity;
- extractables and leachables;
- sterilisation compatibility;
- biocompatibility or toxicological profile;
- stability throughout the shelf life.

For plastic transport and group packaging, suppliers are required to provide information on the recycled-content percentage and the calculation method used.

Justification for Non-applicability to the Sterile Barrier System

"The requirement for minimum recycled plastic content under Article 7(1) and (2) PPWR is not applicable to the plastic layers of the sterile barrier system pursuant to the exemption in Article 7(4)(b), as these constitute contact-sensitive plastic packaging for a medical device within the meaning of Regulation (EU) 2017/745."

Residual Risk

P = 1, S = 3, R = 3 – Medium, acceptable provided that the legal basis for the exemption and the functional necessity of the materials are documented.

8.3.4 Compostability – Article 9 PPWR

Identified Hazard

The packaging could be incorrectly declared as compostable or labelled in a manner that leads users to dispose of it as biowaste, even though it:
does not meet the requirements for industrial composting;
is not suitable for home composting;
contains non-compostable layers; or
contaminates biological waste streams or material recycling streams.

Risk Assessment

Packaging under assessment	Relevance	P	S	R	Evaluation
Sterile barrier system – primary, secondary and tertiary packaging	No	1	1	1	Not applicable
Paper carton	No, provided it is not claimed to be compostable	1	1	1	Not applicable
Group packaging	No, provided it is not claimed to be compostable	1	1	1	Not applicable
Transport packaging	No, provided it is not claimed to be compostable	1	1	1	Not applicable

Justification for Non-applicability

"Article 9 PPWR is not applicable because the packaging does not fall within the packaging formats for which PPWR requires industrial compostability and is neither designed, placed on the market nor labelled as compostable."

Evidence for Verification

- packaging specifications;
- approved packaging texts and symbols;
- artwork documentation;
- marketing claims;
- instructions for disposal.

Risk Control Measures

No claims such as "compostable", "biodegradable", or similar statements are used unless supported by appropriate evidence.

The packaging is not marked with symbols intended for biological waste.

A new assessment shall be carried out whenever the packaging material or any environmental claim is changed.

Residual Risk

P = 1, S = 1, R = 1 – Low.

8.3.5 Minimisation of Packaging Weight and Volume – Article 10 and Annex IV

PPWR

Identified Hazard

The weight or volume of the packaging may exceed the minimum necessary to fulfil its intended function. Typical risk factors include:

- unnecessary packaging layers;
- excessive film thickness;
- oversized cartons;
- double walls;
- false bottoms;
- unnecessary inserts;
- packaging elements intended solely to increase the perceived size of the product.

Article 10 does not provide a general exemption for medical device packaging. However, safety, hygiene, product protection, legal requirements and maintenance of sterility are explicitly recognised as legitimate functional criteria under Annex IV.

Risk Assessment

Packaging under assessment	Relevance	P	S	R	Evaluation
Sterile barrier system – primary, secondary and tertiary packaging	Yes	2	2	4	Medium
Paper carton	Yes	2	2	4	Medium
Group packaging	Yes	2	2	4	Medium
Transport packaging	Yes	2	2	4	Medium

Evidence for Verification

- dimensional drawings of the packaging;
- weight of each packaging layer;
- total packaging weight;
- dimensions of the product and packaging;
- calculation of the packaging-to-product ratio;
- validation reports for the sterile barrier system;
- seal strength and integrity test reports;
- transport and distribution test reports;
- sterilisation validation studies;
- accelerated and real-time ageing studies;
- assessment of the space required for MDR labelling;
- assessment of the space required for the Instructions for Use;
- justification for every packaging layer and packaging component.

Risk Control Measures

- Each layer of the sterile barrier system has a documented function, including:
- microbial barrier;
- permeability to the sterilisation medium;
- moisture protection;

- mechanical protection;
- sealing layer;
- support for aseptic opening;
- resistance to sterilisation;
- stability throughout the declared shelf life.
- Any further reduction in thickness, dimensions or number of packaging layers is considered unacceptable where it could result in:
 - loss of package integrity;
 - reduced seal strength;
 - transport damage;
 - loss of sterility;
 - impaired aseptic opening;
 - insufficient readability of mandatory labelling;
 - non-compliance with the MDR or applicable harmonised standards.

For the secondary packaging, the space required for mandatory information, including UDI, sterilisation information, batch number, expiry date and other required markings, has been assessed.

For group and transport packaging, the number of packaged units per carton, palletisation and utilisation of transport space are optimised.

The packaging design is reviewed whenever a new product is introduced or whenever significant changes are made to the product, packaging or distribution conditions.

Conclusion of the Packaging Minimisation Assessment for the Sterile Barrier System

"The current number of packaging layers, dimensions and weight of the sterile barrier system represent the functional minimum necessary. Any further reduction could adversely affect the integrity of the sterile barrier, the sealing process, sterilisation compatibility, mechanical protection, microbial barrier performance, aseptic presentation or stability throughout the declared shelf life."

Residual Risk

P = 1, S = 3, R = 3 – Medium, acceptable on the basis of validation data and documented design evidence.

8.3.6 Reuse – Articles 11, 26 and 29 PPWR

Identified Hazard

- The packaging could be incorrectly labelled or presented as reusable even though it:
 - is not designed for multiple use cycles;
 - cannot be safely cleaned or decontaminated;
 - cannot be refilled without compromising safety;
 - is not part of a reuse system;
 - has no defined number of reuse cycles; or
 - is not supported by a collection, inspection, cleaning and redistribution system.

A single-use sterile barrier system cannot be reused without compromising the sterile barrier and without a new validated packaging and sterilisation process.

Risk Assessment

Packaging under assessment	Relevance	P	S	R	Evaluation
Sterile barrier system – primary, secondary and tertiary packaging	No	1	1	1	Not applicable
Paper carton	No	1	1	1	Not applicable
Group packaging	Potentially applicable depending on the packaging format and distribution model	2	2	4	Medium
Transport packaging	Potentially applicable depending on the packaging format and distribution model	2	2	4	Medium

Evidence for Verification

- packaging specifications and intended purpose;
- packaging texts and labelling;
- marketing claims;
- distribution model;
- inventory of transport packaging, films and securing materials.

Risk Control Measures

The sterile barrier system is clearly designated as single-use packaging.

The packaging is not labelled or marketed as reusable.

For transport cartons, it is recognised that Article 29 contains specific exemptions and different requirements depending on the material and packaging format. Therefore, not all transport packaging is automatically subject to the reuse targets.

Justification for Non-applicability to the Sterile Barrier System

"Article 11 PPWR is not applicable to the sterile barrier system because the packaging is neither designed, placed on the market nor labelled as reusable. Opening the packaging irreversibly compromises the sterile barrier."

Residual Risk

P = 1, S = 2, R = 2 – Low, except for transport packaging formats that may become subject to future reuse targets.

8.3.7 Packaging Labelling – Article 12 PPWR

Identified Hazard

The packaging may:

- bear an incorrect material identification symbol;
- be labelled in accordance with technical rules that have not yet entered into force;

- contain incomplete labelling;
- contain labelling that conflicts with the MDR;
- include misleading claims regarding recyclability, compostability or recycled content; or
- contain symbols that reduce the readability of mandatory information or compromise the safe use of the medical device.

The harmonised material composition labelling requirements will apply from the date specified in Article 12(1), i.e. 12 August 2028, or 24 months after the entry into force of the relevant implementing acts, whichever is later.

Article 12 does not apply to the immediate and outer packaging of medical devices where insufficient space remains due to mandatory MDR labelling or where additional labelling could compromise the safe use of the device.

According to the European Commission guidance:

immediate packaging means packaging that is in direct contact with the medical device;

outer packaging means the sales packaging of the medical device.

Risk Assessment

Packaging under assessment	Relevance	P	S	R	Evaluation
Sterile barrier system – primary, secondary and tertiary packaging	No – exemption applies	1	1	1	Not applicable
Paper carton	Labelling required under Article 15(11)	2	1	2	Low
Group packaging	Labelling required under Article 15(11)	2	1	2	Low
Transport packaging	Labelling required under Article 15(11)	2	1	2	Low

Evidence for Verification

approved artwork documentation;

list of mandatory MDR information;

dimensional assessment of available labelling space;

current implementing acts and harmonised symbols;

review of environmental marketing claims;

supporting evidence for any claims regarding recyclability or recycled content.

Risk Control Measures

1. The Regulatory Department monitors the publication of the implementing acts under Article 12(6) and 12(7).
2. The application of the exemption under Article 12(11) is justified separately for each packaging format.
3. Environmental claims are used only where they are clearly defined, substantiated and not misleading.
4. Claims relating solely to the transport carton shall not create the impression that the entire packaging system is recyclable.

Recommended Justification for the Exemption

"The requirements of Article 12 PPWR do not apply to the immediate sterile packaging pursuant to Article 12(11), because the available surface area is required for the mandatory medical device labelling under Regulation (EU) 2017/745, and the addition of further labelling could reduce the readability of mandatory information or adversely affect the safe and aseptic use of the medical device."

The exemption cannot be justified solely by stating that the product is a medical device. It must be supported by evidence of insufficient available space or by demonstrating a risk to the safe use of the device.

Residual Risk

P = 1, S = 3, R = 2 – Low, acceptable provided that legislative developments are regularly monitored and packaging artwork is subject to regulatory approval.

8.3.8 Excess Empty Space – Article 24 PPWR

Identified Hazard

Group and transport packaging may exceed the maximum permitted 50% empty space ratio. Empty space also includes space filled with, for example: paper cushioning; bubble wrap; The 50% limit will apply from 1 January 2030 or three years after the entry into force of the relevant implementing act, whichever is later.

In addition, Article 24(4) requires, from 12 February 2028, that the empty space within sales packaging be reduced to the minimum necessary to preserve the packaging's intended function.

Risk Assessment

Packaging under assessment	Relevance	P	S	R	Evaluation
Sterile barrier system – primary, secondary and tertiary packaging	Yes	1	2	2	Low
Paper carton	Yes	2	1	2	Low
Group packaging	Yes	2	1	2	Low
Transport packaging	Yes	2	1	2	Low

Evidence for Verification

- internal dimensions of the packaging;
- external dimensions of all packed sales units;
- number of units contained in the package;
- calculation of the empty-space volume;
- description and volume of cushioning and securing materials;
- photographs of the standard packaging configuration.

Risk Control Measures

A standard packing configuration shall be defined for every group and transport package. The number of sales units per shipping carton shall be optimised to minimise unused internal volume. Cushioning materials shall only be used where necessary to prevent damage during transport. The dimensions of shipping cartons shall be reviewed whenever the product dimensions, packaging

configuration or transport conditions change.

Compliance with the maximum permitted empty-space ratio shall be reassessed before the Article 24 requirements become applicable.

Residual Risk

P = 1, S = 1, R = 1 – Low, acceptable provided that transport packaging dimensions continue to be reviewed and optimised.

8.4 Summary

Requirement	Sterile System (Primary, Secondary Packaging)	Barrier (Primary, Secondary Packaging)	Paper Box	Group Packaging	Transport Packaging
Article 5 – Substances in Packaging	Applicable		Applicable	Applicable	Applicable
Article 5(5) – PFAS for Food Contact Packaging	Not applicable unless the packaging is intended for food contact		Not applicable	Not applicable	Not applicable
Article 6 – Recyclability	Exempt as contact-sensitive medical device packaging		Applicable	Applicable	Applicable
Article 7 – Recycled Plastic Content	Exempt as contact-sensitive plastic packaging for medical devices		Applicable to plastic components	Applicable to plastic components	Applicable to plastic components
Article 9 – Compostability	Not applicable		Not applicable	Not applicable	Not applicable
Article 10 – Minimisation of Packaging Weight and Volume	Applicable		Applicable	Applicable	Applicable
Article 11 – Properties of Reusable Packaging	Not applicable to single-use packaging		Not applicable	Applicable	Applicable
Article 26 – Obligations for Reusable Packaging	Not applicable		Not applicable	Applicable	Applicable
Article 29 – Reuse Targets	Not applicable		Not applicable	Applicable	Applicable
Article 12 – Packaging Labelling	Potential exemption		Applicable	Applicable	Applicable
Article 24 – Empty Space	Limited applicability		Applicable pursuant to	Applicable	Applicable

The risk assessment performed demonstrates that the packaging has been evaluated against all relevant requirements of Regulation (EU) 2025/40 (PPWR) applicable to the packaging of medical devices.

Where PPWR provides specific exemptions for medical devices, these have been identified, documented and justified in accordance with the relevant provisions of the Regulation.

For the remaining applicable requirements, appropriate technical documentation, supplier declarations, design documentation, validation reports and material specifications have been established to demonstrate conformity.

The identified residual risks are considered acceptable, provided that:

- supplier qualification and change control procedures are maintained;
- packaging design changes continue to be assessed through the established design control process;
- applicable legislative developments, implementing acts and harmonised specifications are continuously monitored;
- the technical documentation is updated whenever changes to packaging materials, suppliers, manufacturing processes or applicable legislation occur.

Based on the available evidence, the residual risks associated with compliance of the packaging with the applicable PPWR requirements are considered acceptable, and no additional risk control measures are currently required.

9 List of attachments

9.1 Primary packaging

9.1.1 Technical Data Sheets

- ARHA Technical Data Sheet
- The roll – Film PA/PE U Standard
- The roll – Film PA/PE U Standard, peel
- Material safety data sheet Thermal Transfer Ribbons (TTR Ribbons), types WAX, WAX/RESIN and RESIN
- TFP Universal TECHNICAL SPECIFICATIONS OF THERMAL TRANSFER RIBBON WAX - RESIN NEAR EDGE

9.1.2 Declarations of Compliance

- ARHA Declaration of Compliance (MED_05-2022)
- Prohlášení o shodě – PA/PE_U (verze 2026/245)
- TECHNICAL DOCUMENTATION / DECLARATION OF CONFORMITY

9.1.3 Certificates

- ARHA Certificate of Analysis

9.1.4 PPWR statements

- AFEMEA Position on Compliance with the PPWR (March 2025)
- AMCOR Position Statement: Compliance with the Packaging and Packaging Waste Regulation (April 2026)

9.2 Secondary packaging

9.2.1 Technical Data Sheets

- ARHA Technical Data Sheet
- The roll – Film PA/PE U Standard, peel
- Material safety data sheet Thermal Transfer Ribbons (TTR Ribbons), types WAX, WAX/RESIN and RESIN
- TECHNICAL SPECIFICATIONS OF THERMAL TRANSFER RIBBON WAX - RESIN NEAR EDGE

9.2.2 Declarations of Compliance

- ARHA Declaration of Compliance (MED_05-2022)
- Prohlášení o shodě – PA/PE_U (verze 2026/245)
- TFP Universal TECHNICAL DOCUMENTATION / DECLARATION OF CONFORMITY

9.2.3 Certificates

- ARHA Certificate of Analysis

9.2.4 PPWR statements

- AFEMEA Position on Compliance with the PPWR (March 2025)
- AMCOR Position Statement: Compliance with the Packaging and Packaging Waste Regulation (April 2026)

9.3 Paper box

9.3.1 Packaging Technical Specifications

- Paper box specification Alaska

9.3.2 Declarations of Compliance

- Declaration of compliance Polyra PPWR

9.3.3 Certificates

- FSC certificate Polygra

9.3.4 PPWR statements

- Product Safety Statement – ALASKA WHITE / Virgin Fibre Cartonboard (MM BOARD & PAPER)

9.4 Group packaging

9.4.1 Technical Data Sheets

- Probas technical specification paperboard master box

9.4.2 Declarations of Compliance

- Probas Conformity declaration EU 2025/40 (CZ)

9.5 Labels for Paper box

- DATASHEET R0502 + glue
- Packaging declaration Rayfilm

9.6 Labels for Paper box with UDI

- DATASHEET R0100-2026 with stronger glue
- Packaging declaration Rayfilm

9.7 Labels for Group packaging box

- DATASHEET R0100-2026 with stronger glue
- Packaging declaration Rayfilm

9.8 Labels for transport box

- DATASHEET R0100-2026 with stronger glue
- Packaging declaration Rayfilm

9.9 IFU

- Declaration of compliance Polyra PPWR

9.10 Round colour-coding label – green

- DATASHEET R0120_2025
- Packaging declaration Rayfilm

9.11 Round colour-coding label – blue

- DATASHEET R0123
- Packaging declaration Rayfilm

9.12 Transport packaging

9.12.1 Technical Data Sheets

- Probas technical specification paperboard master box
- Etigam sterilization indicators
- Etigam material safety data sheet

9.12.2 Declarations of Compliance

- **Probas** Conformity declaration EU 2025/40 (CZ)

9.12.3 Certificates

- Europapier Austria FSC Certificate
- Europapier Austria PEFC Certificate

10 Archiving and availability of documentation

Place of storage of documentation:

Form of storage (electronic / paper)

Retention period: at least 5 years