

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

Product name: Traumastem POWDER
Traumastem P

Manufacturer: BIOSTER, a.s.
Tejny 621
664 71 Veverská Bítýška
Czech Republic

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List of revisions

Revision	Revision date	Change description	Author

1. List of Packaging Components

Plastic bellows bottle

Secondary packaging

Tertiary packaging

Thermal transfer ribbon

Attachment label

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
Plastic bellows bottle	Forms part of the sterile barrier. Protective packaging that helps maintain product protection until use.	Inner packaging	Yes	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Secondary packaging	Forms part of the sterile barrier. Protective packaging that helps maintain product protection until use.	Inner packaging	Yes	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Tertiary packaging	Forms part of the sterile barrier. Protective packaging that helps maintain product protection until use.	Inner packaging	Yes	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Attachment label	Sticker card, stickers with the information about used product to patient documentation		Yes	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Thermal transfer ribbon	Printing consumable used to print variable information on labels or packaging.		No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Paper box	Serves as sales-unit packaging;	Sales packaging	No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG

	contains and protects the packaged product and carries product information.			
Label for paper box	Provides product identification, traceability and required labelling information.		No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Label for paper box with UDI	Provides product identification, traceability and required labelling information.		No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Group packaging box	Groups packaged units and protects them during storage, handling and transport.	Group packaging	No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Label for group packaging box	Provides product identification, traceability and required labelling information.		No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Transport carton	Groups packaged units and protects them during storage, handling and transport.	Transport packaging	No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Label for transport carton	Provides product identification, traceability and required labelling information.		No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Package leaflet / instructions for use	Provides user information, instructions for use, warnings and precautions.		No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG

Round blue label	Indicates finished batch		No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Round green label	Indicates released batch		No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Transparent adhesive sealing tape	Seals outer cartons for storage, handling and transport.	Transport packaging	No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Stretch film	Protects carton boxes during transport.	Transport packaging	No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Polypropylene strapping	Holds carton boxes during transport on wooden pallet	Transport packaging	No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Bubble wrap	Cushions products and protects them against impact and movement.	Transport packaging	No	ES/GR/PL/PT/ CZ/SK/RO/HU/BG
Paper void fill	Fills empty space and prevents product movement inside the box.	Transport packaging	NO	ES/GR/PL/PT/ CZ/SK/RO/HU/BG

2.2 Variants of Packaging Components

Packaging component	Variant
Plastic bellows bottle	1 variant
Secondary packaging	2 sizes: 155 × 120 mm; 140 × 105 mm
Tertiary packaging	1 size: 210 × 140 mm
Paper box	2 sizes: 222 × 153 × 82 mm; 142 × 118 × 82 mm
Label for paper box	1 size: 36 × 70 mm
UDI label for paper box	1 size: 36 × 30 mm
Group packaging carton	2 sizes: 315 × 229 × 342 mm; 241 × 291 × 342 mm
Label for group packaging carton	1 size: 148 × 105 mm

Transport carton	2 sizes: 770 × 390 × 295 mm; 590 × 390 × 388 mm
Label for transport carton	1 size: 148 × 105 mm
Instructions for Use (IFU)	1 format: 50 × 40 mm
Transparent adhesive sealing tape	1 type: width 50 mm
Shrink film	1 type: width 500 mm, thickness 12 µm
Strapping band	1 type: width 12 mm, thickness 0,5 mm

2.3 Identification Codes of Packaging Components

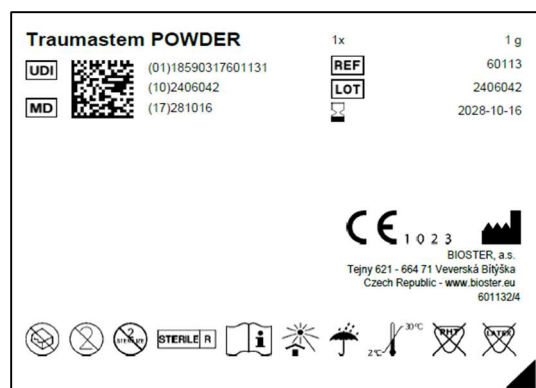
Not all packaging components have individual identification codes, as certain packaging materials cannot be practically marked or printed..

REF	Name of the product	Variant	Size	Secondary packaging code	Tertiary packaging code	Box code	Label on the paper box	Label on the paper box with UDI	Group packaging box	Label for group packaging box	Transport carton	Label for transport carton	Package leaflet / instructions for use
60263	Traumastem POWDER	bellows pouch	1g	602632/4	602634/4	mz1124/2	602635/3	602636/3	mz1094/	mz1124/3	mz164 mz875	6026310/4	mz1064/4
60264	Traumastem POWDER	bellows pouch	2g	602642/4	602644/4	mz1124/2	602645/3	602646/3	mz1094/	mz1124/3	mz164 mz875	6026410/4	mz1064/4
60265	Traumastem POWDER	bellows pouch	3g	602652/4	602654/4	mz1124/2	602655/3	602656/3	mz1094/	mz1124/3	mz164 mz875	6026510/4	mz1064/4
60266	Traumastem POWDER	bellows pouch	5g	602662/4	602664/4	mz1124/2	602665/3	602666/3	mz1094/	mz1124/3	mz164 mz875	6026610/4	mz1064/4
60112	Traumastem POWDER	bellows pouch I	2 g	601122/4	601124/4	mz1124/2	601125/3	601126/3	mz1094/	mz1124/3	mz164 mz875	6011210/4	mz1064/4
60113	Traumastem POWDER	bellows pouch I	1 g	601132/4	601134/4	mz1124/2	601135/3	601136/3	mz1094/	mz1124/3	mz164 mz875	6011310/4	mz1064/4
60114	Traumastem POWDER	bellows pouch I	3 g	601142/4	601144/4	mz1124/2	601145/3	601146/3	mz1094/	mz1124/3	mz164 mz875	6011410/4	mz1064/4
60115	Traumastem POWDER	bellows pouch I	5 g	601152/4	601154/4	mz1124/2	601155/3	601156/3	mz1094/	mz1124/3	mz164 mz875	6011510/4	mz1064/4
60111	Traumastem P	bellows pouch I	2 g	601112/4	x	mz1222/1	601115/3	601116/3	mz1194/	mz1222/3	mz164	6011110/4	mz1122/4
60105	Traumastem P	bellows pouch I	1 g	601052/4	x	mz1222/1	601055/3	601056/3	mz1194/	mz1222/3	mz164	6010510/4	mz1122/4
60106	Traumastem P	bellows pouch I	3 g	601062/4	x	mz1222/1	601065/3	601066/3	mz1194/	mz1222/3	mz164	6010610/4	mz1122/4
60107	Traumastem P	bellows pouch I	5 g	601072/4	x	mz1222/1	601075/3	601076/3	mz1194/	mz1222/3	mz164	6010710/4	mz1122/4

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

Traumastem POWDER – Bellows Pouch I Variant

Primary Packaging	Bellows-type bottle containing haemostatic powder. Bottle material: LDPE + EVA REPSOL PRIMEVA P1340 (polyethylene) Closure material: LDPE RIBLENE MV 10 R EVA REPSOL PRIMEVA P1340 (polyethylene) Remafin White PK6-AE 
Secondary Packaging	Sterile pouch containing the bellows bottle filled with haemostatic powder made of oxidized regenerated cellulose calcium salt. 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 secondary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of Use Manufacturer Distributor (where applicable), artwork code, symbols required for safe use, transport symbols storage symbols



The tertiary package consists of a sterile pouch containing the secondary packaged haemostatic powder.

Packaging material

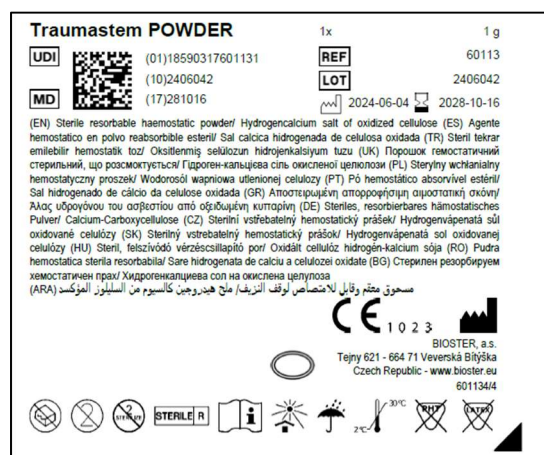
Vacuum laminate: PA/PE 3090 + MEDIFLEX Type ARHA

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 Distributor (where applicable), artwork code, symbols required for safe use, transport symbols storage symbols, composition.

Tertiary Packaging



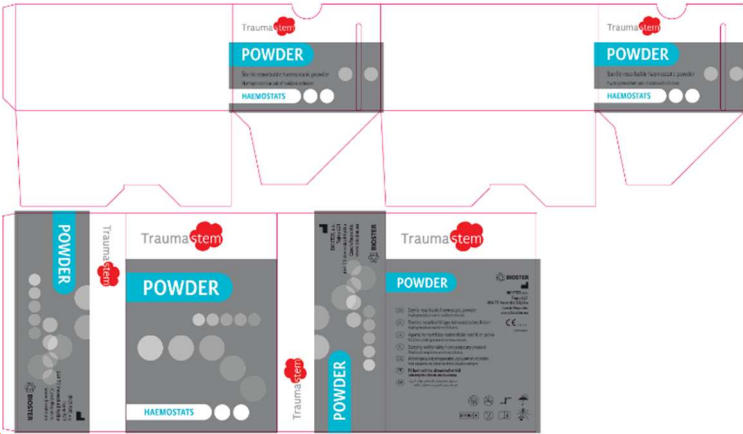
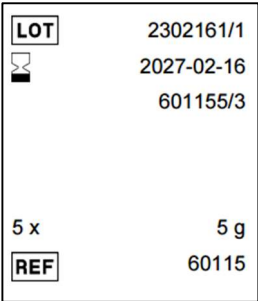
The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper carton represents the sales unit.

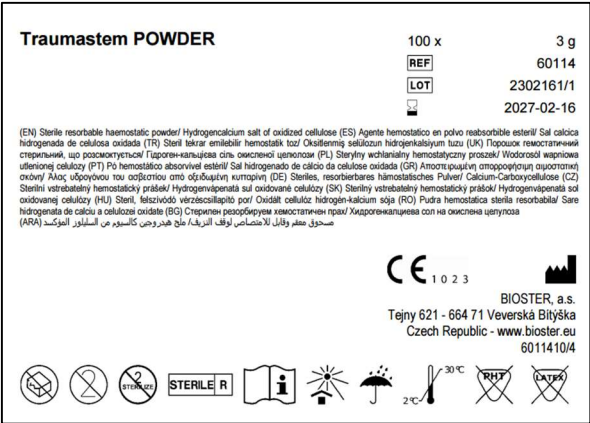
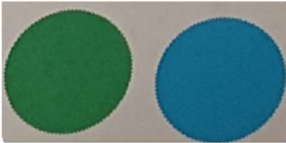
Artwork for all cartons is included in:

Chapter 5 – Packaging Materials, Labelling and Validation

Contents of one sales package: 5 bellows bottles

Printed paper box

	Instructions for Use (IFU) 
Label for the Paper Box	Each paper carton carries a label including: Batch number, expiry date, artwork code, quantity per box  REF number
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 
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.
Group Packaging Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, distributor (where applicable), artwork code, symbols for safe use, transport symbols storage symbols

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, distributor (where applicable), artwork code, symbols for safe handling, transport symbols, storage symbols 
Round blue label Round green label	Material: Paper 

Traumastem POWDER – varianta bellows pouch

Primary Packaging	Lahvička harmonikového tvaru obsahující hemostatický prášek. Složení lahvičky: LDPE PURELL PE 1840 H + EVA (polyethylene) Složení uzávěru: HDPE Pharmalene MP 90 PH
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Secondary Packaging

Sterile pouch containing the bellows bottle filled with haemostatic powder made of oxidized regenerated cellulose calcium salt.

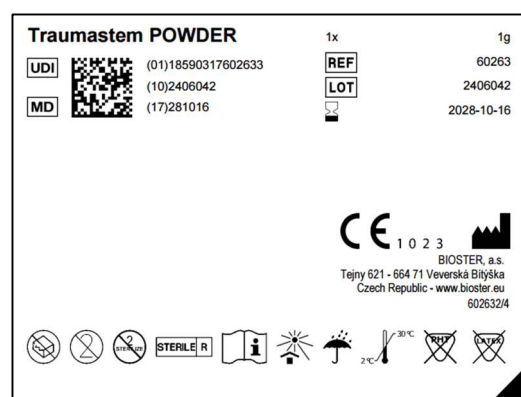
Packaging material

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 secondary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of Use Manufacturer Distributor (where applicable), artwork code, symbols required for safe use, transport symbols storage symbols



Tertiary Packaging

The tertiary package consists of a sterile pouch containing the secondary packaged haemostatic powder.

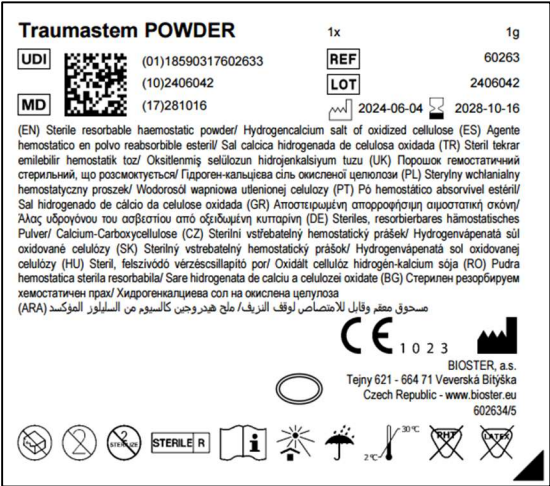
Packaging material

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 Distributor (where applicable), artwork code, symbols required for safe use, transport symbols storage symbols, composition.



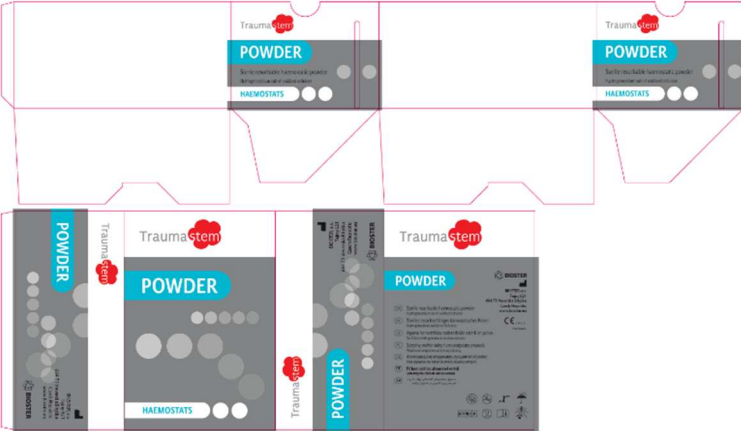
The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper carton represents the sales unit.

Artwork for all cartons is included in:

Chapter 5 – Packaging Materials, Labelling and Validation

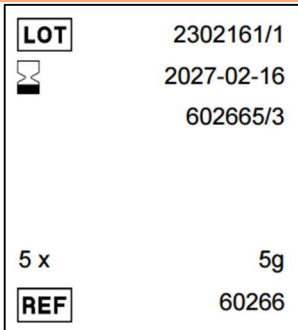
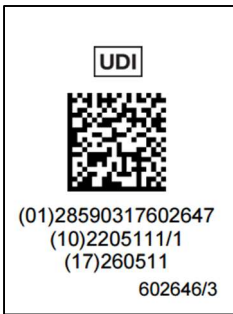
Contents of one sales package: 5 bellows bottles

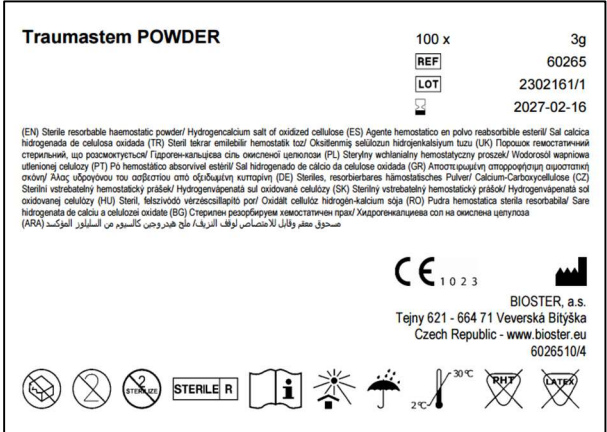
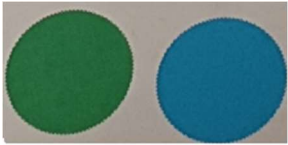
Instructions for Use (IFU)



Label for the Paper Box

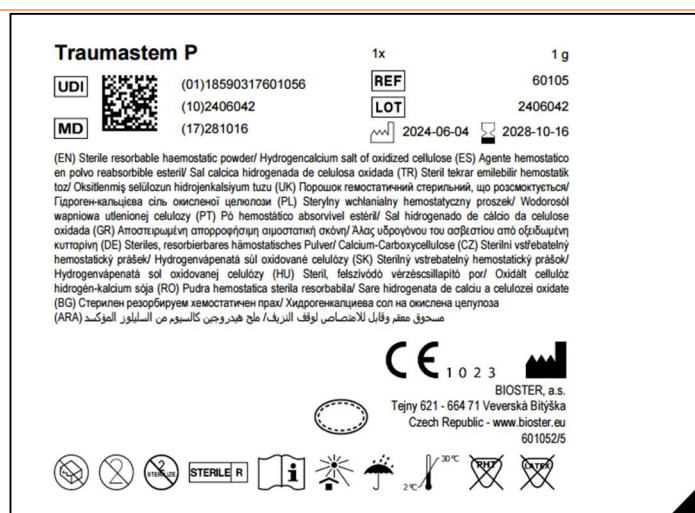
Each paper carton carries a label including: Batch number, expiry date, artwork code, quantity per box

	
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. 
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.
Group Packaging Label	The label contains: REF number, product name, product size, quantity, batch number, expiry date, UDI – Group Package, product description, manufacturer, distributor (where applicable), artwork code, symbols for safe use, transport symbols storage symbols 

Transport carton	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, distributor (where applicable), artwork code, symbols for safe handling, transport symbols, storage symbols. 				
Transport Carton Label	Material : Corrugated paper <table border="1" data-bbox="456 848 1151 1083"> <tr> <td>carton 590x390x388 mz164</td><td>carton 770x390x 295 mm mz875</td></tr> <tr> <td>≤ 2 pcs shipping boxes</td><td>≤ 3 pcs shipping boxes mz 875</td></tr> </table> Maximum 15 cartons per pallet, 3 cartons per level Example of pallet storage.  	carton 590x390x388 mz164	carton 770x390x 295 mm mz875	≤ 2 pcs shipping boxes	≤ 3 pcs shipping boxes mz 875
carton 590x390x388 mz164	carton 770x390x 295 mm mz875				
≤ 2 pcs shipping boxes	≤ 3 pcs shipping boxes mz 875				
Round blue label Round green label	Material: Paper 				

Traumastem P

Primary Packaging	Bellows-type bottle containing haemostatic powder. Bottle material: LDPE + EVA REPSOL PRIMEVA P1340 (polyethylene) Closure material: LDPE RIBLENE MV 10 R EVA REPSOL PRIMEVA P1340 (polyethylene) Remafin White PK6-AE 
Secondary Packaging	Sterile pouch containing the bellows bottle filled with haemostatic powder made of oxidized regenerated cellulose calcium salt. 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 secondary package includes: REF number, product name, product size batch number (LOT), expiry date UDI – Unit of Use Manufacturer Distributor (where applicable), artwork code, symbols required for safe use, transport symbols storage symbols



Tertiary Packaging

None

Printed paper box

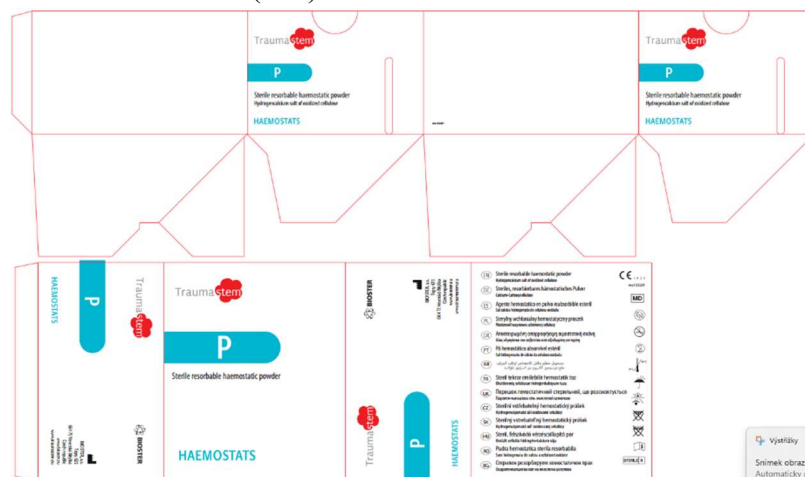
The paper box contains a defined number of Units of Use packaged in the primary and secondary packaging. The product packed in the paper carton represents the sales unit.

Artwork for all cartons is included in:

Chapter 5 – Packaging Materials, Labelling and Validation

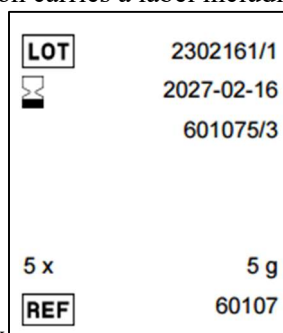
Contents of one sales package: 5 bellows bottles

Instructions for Use (IFU)

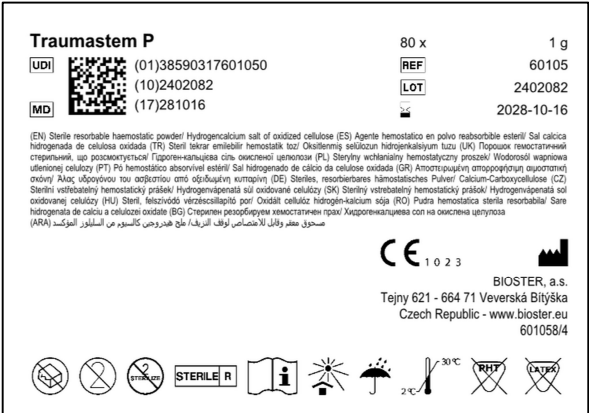


Label for the Paper Box

Each paper carton carries a label including: Batch number, expiry date, artwork code,

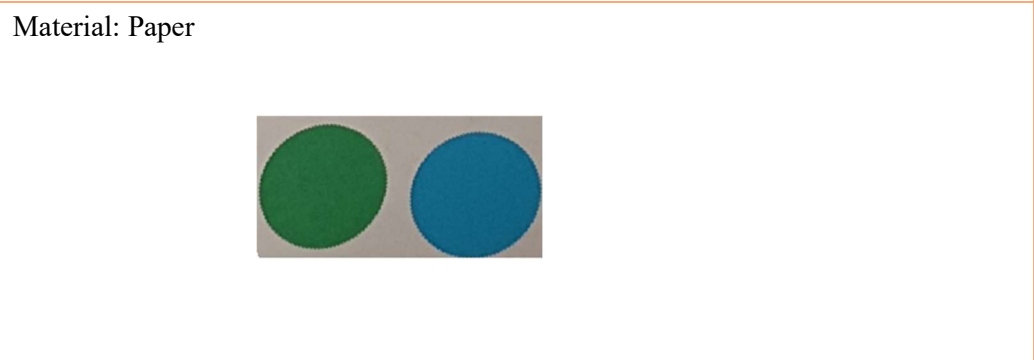


quantity per box

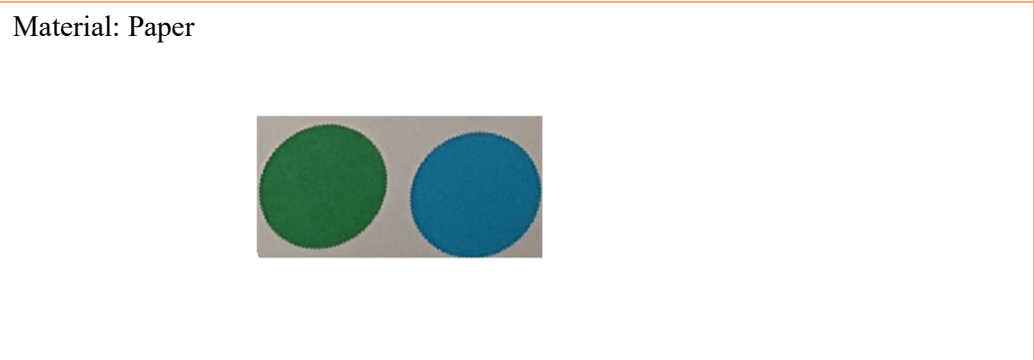
UDI Label for the Paper Box	Each paper carton additionally carries a UDI label containing: UDI symbol, GS1 DataMatrix, GTIN-14, application identifiers, batch number, expiry date, artwork code 
Group Packaging Carton	The group packaging carton together with the corresponding group packaging label constitutes the group packaging unit containing a predefined number of sales units.
Group Packaging Label	Etiketa obsahuje: REF, název výrobku, rozměr, počet kusů ve skupinovém balení, číslo šarže, expiraci, UDI – skupinové balení, popis, výrobce, distributor (pokud je určen), kód potisku, symboly pro správné použití, transport a skladování. 
Transport carton	Material: Corrugated paper, size: 590x390x388 

Transport Carton Label
Round blue label Round green 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, distributor (where applicable), artwork code, symbols for safe handling, transport symbols, storage symbols



Material: Paper



4. Material Composition

4.1 Materials Used

Traumastem POWDER – variant bellows pouch and bellows pouch I

Name of the packaging	Packaging description	Composition	Producer
Plastic bellows bottle	Polyethylene bottle	Material: LDPE PURELL PE 1840 H + EVA (polyethylene + ethylenvinylacetát) Složení uzávěru: HDPE Pharmalene MP 90 PH	Lameplast
Thermal transfer ribbon	Printing consumable used to print variable information on labels or packaging.	Polyester	TFP Universal a.s.
Secondary packaging	PA/PE vacuum packaging film	PA/PE 3090: polyamid, polyethylen MEDIFLEX typ ARHA: papír, adhesivum, Rayopeel Y/R1	Vepak, s.r.o. Ampcor
Tertiary packaging	PA/PE vacuum packaging film	PA/PE 3090: polyamid, polyethylen MEDIFLEX typ ARHA: papír, adhesivum, Rayopeel Y/R1	Vepak, s.r.o. Ampcor
Attachment label	Sticker card	Paper	Rayfilm s.r.o.
Paper box	Printed folded box	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.	Polyester	Rayfilm s.r.o.
Group packaging carton	Corrugated transport carton	Paper	Probas, s.r.o.
Label for group packaging carton	Self-adhesive label	Paper	Rayfilm s.r.o.

Transport carton	Corrugated transport carton	Paper	Probas, s.r.o.
Label for transport carton	Self-adhesive label	Paper	Rayfilm s.r.o.
Package leaflet / instructions for use	Provides user information, instructions for use, warnings and precautions.	Paper	Polygra, a.s.
Gamma irradiation indicator label	Indicates exposure of the package or batch to gamma irradiation during sterilization.	Paper	Etigam BV
Transparent adhesive sealing tape	Seals outer cartons for storage, handling and transport.	Polypropylene	Europapier
Round blue label	Indicates finished batch	Paper	Rayfilm s.r.o.
Round green label	Indicates released batch	Paper	Rayfilm s.r.o.
Shrink wrap	Protects carton boxes during transport.	Transport packaging	Europapier
Binding strap	Holds carton boxes during transport on wooden pallet	Transport packaging	Europapier

Traumastem P

Name of the packaging	Packaging description	Composition	Producer
Plastic bellows bottle	Polyethylene bottle	Material: LDPE PURELL PE 1840 H + EVA (polyethylene + ethylenvinylacetát) Složení uzávěru: HDPE Pharmalene MP 90 PH	Lameplast
Thermal transfer ribbon	Printing consumable used to print variable	Polyester	TFP Universal a.s.

	information on labels or packaging.		
Secondary packaging	PA/PE vacuum packaging film	PA/PE 3090: polyamid, polyethylen MEDIFLEX typ ARHA: papír, adhesivum, Rayopeel Y/R1	Vepak, s.r.o. Amcor
Attachment label	Sticker card	Paper	Rayfilm s.r.o.
Paper box	Printed folded box	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.	Polyester	Rayfilm s.r.o.
Group packaging carton	Corrugated transport carton	Paper	Probas, s.r.o.
Label for group packaging carton	Self-adhesive label	Paper	Rayfilm s.r.o.
Transport carton	Corrugated transport carton	Paper	Probas, s.r.o.
Label for transport carton	Self-adhesive label	Paper	Rayfilm s.r.o.
Package leaflet / instructions for use	Provides user information, instructions for use, warnings and precautions.	Paper	Polygra, a.s.
Gamma irradiation indicator label	Indicates exposure of the package or batch to gamma irradiation during sterilization.	Paper	Etigam BV
Transparent adhesive sealing tape	Seals outer cartons for storage, handling and transport.	Polypropylene	Europapier
Round blue label	Indicates finished batch	Paper	Rayfilm s.r.o.
Round green label	Indicates released batch	Paper	Rayfilm s.r.o.
Shrink wrap	Protects carton boxes during transport.	Transport packaging	Europapier

Binding strap	Holds carton boxes during transport on wooden pallet	Transport packaging	Europapier
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Material specifications and supplier certificates are included in the Annexes.

4.2 Material Composition by Packaging Configuration

Traumastem POWDER – variant bellows pouch

Name of the packaging	Weight of packaging	Weight of packaging per 1 pc g	Weight share %	Share of recycled material in %
Plastic bellows bottle	8,1	8,10	10,46	0
Thermal transfer ribbon				0
Secondary packaging	4,2	4,20	5,42	0
Tertiary packaging	7,5	7,50	9,69	0
Paper box	78	15,60	20,15	0
Label for paper box	0,2	0,04	0,05	0
Label for paper box with UDI	0,1	0,02	0,03	0
Group packaging carton	235	14,69	18,97	70
Label for group packaging carton	1,3	0,08	0,10	0
Transport carton	846	26,44	34,14	70
Label for transport carton	1,3	0,04	0,05	0
Package leaflet / instructions for use	3,6	0,72	0,93	0
Gamma	0,01	0,00	0,00	0

irradiation				
indicator label				
Transparent adhesive sealing tape	variable	variable	variable	0
Round blue label	0,01	0,00	0,00	0
Round green label	0,01	0,00	0,00	0
Shrink wrap	variable	variable	variable	0
Binding strap	variable	variable	variable	0

Traumastem POWDER – variant bellows pouch I

Name of the packaging	Weight of packaging	Weight of packaging per 1 pc g	Weight share %	Share of recycled material in %
Plastic bellows bottle	5,9	5,90	7,84	0
Thermal transfer ribbon	0			0
Secondary packaging	4,2	4,20	5,58	0
Tertiary packaging	7,5	7,50	9,97	0
Paper box	78	15,60	20,74	0
Label for paper box	0,2	0,04	0,05	0
Label for paper box with UDI	0,1	0,02	0,03	0
Group packaging carton	235	14,69	19,52	70
Label for group packaging carton	1,3	0,08	0,11	0
Transport carton	846	26,44	35,14	70
Label for transport carton	1,3	0,04	0,05	0
Package leaflet / instructions for use	3,6	0,72	0,96	0
Gamma irradiation	0,01	0,00	0,00	0

indicator label				
Transparent adhesive sealing tape	variable	variable	variable	0
Round blue label	0,01	0,00	0,00	0
Round green label	0,01	0,00	0,00	0
Shrink wrap	variable	variable	variable	0
Binding strap	variable	variable	variable	0

Traumastem P

Name of the packaging	Weight of packaging	Weight of packaging per 1 pc g	Weight share %	Share of recycled material in %
Plastic bellows bottle	5,9	5,90	10,07	0
Thermal transfer ribbon				0
Secondary packaging	3,8	3,80	6,49	0
Tertiary packaging	-			
Paper box	45	9,00	15,37	0
Label for paper box	0,2	0,04	0,07	0
Label for paper box with UDI	0,1	0,02	0,03	0
Group packaging carton	240	15,00	25,61	70
Label for group packaging carton	1,3	0,08	0,14	0
Transport carton	767	23,97	40,92	70
Label for transport carton	1,3	0,04	0,07	0
Package leaflet / instructions for use	3,6	0,72	1,23	0
Gamma irradiation indicator label	0,01	0,00	0,00	0

Transparent adhesive sealing tape	variable	variable	variable	0
Round blue label	0,01	0,00	0,00	0
Round green label	0,01	0,00	0,00	0
Shrink wrap	variable	variable	variable	0
Binding strap	variable	variable	variable	0

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 haemostatic powder is filled into the bellows bottles using a DOS MIKRO dosing machine and a powder screw feeder. The filled bottles are closed using a push-on cap.

The bottles are packed into the secondary packaging using a packaging machine. 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 operators place the filled bottle, the applicator and the folded Instructions for Use into the packaging machine. For the Bellows Pouch I variants, the applicator is not inserted.

The Traumastem POWDER Bellows Pouch I and Traumastem POWDER Bellows Pouch variants are subsequently packed into tertiary packaging. The machine operator selects the tertiary packaging print layout from the machine memory, installs the forming dies, sealing dies and depth-adjustment inserts, and starts the machine. The operators place the products already packed in the secondary packaging into the packaging machine.

Products packed in secondary or tertiary packaging are placed into paper cartons in quantities of five units. The cartons are then labelled.

The cartons are packed into group packaging cartons.

The group packaging cartons are placed into shipping cartons, sealed with PVC adhesive tape and stacked on EUR or standard pallets in several layers. If the shipping cartons are not completely filled, the empty space is filled with cushioning material (bubble wrap or paper). Each shipping carton is identified with an identification label.

5.2 Production Control

The operators inspect the products packed in secondary and tertiary 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	Does not apply to contact-sensitive packaging used for medical devices under the MDR or	No	—

	performance grades.	IVDs under the IVDR (Article 6(11)(b),(c)).		
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 biodegradable packaging should generally remain materially recyclable.	—	No	—
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 MDR/IVDR labelling requirements (Article 12(11)).	—	Yes	The packaging bears the address of the packaging manufacturer.
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.

7.2 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:

$$\mathbf{R = Probability \times Severity}$$

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 box	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

1. 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**.
2. Current material specifications and declarations regarding chemical composition are maintained for each material.
3. Suppliers shall notify any change to formulations, layers, pigments, printing inks, adhesives or surface treatments before implementation.
4. For multilayer packaging, each individual layer and component is assessed separately rather than only the finished laminate.
5. Where the composition is not adequately documented, laboratory testing shall be performed using an appropriate analytical method.
6. 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 box	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

1. The sterile barrier system is clearly identified in the technical documentation as **contact-sensitive packaging for a medical device**.
2. 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.
3. The legal basis for the exemption is documented as **Article 6(11)(b) PPWR**.
 4. Secondary, group and transport packaging are designed, wherever possible, as monomaterial structures or easily separable material combinations.
 5. Only labels, adhesives, varnishes and printing inks that do not significantly impair recyclability are used on paper and paperboard packaging.
 6. 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 box	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

1. The exemption under **Article 7(4)(b)** is documented for the sterile barrier system.
2. 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.
3. 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 box	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

1. No claims such as **"compostable"**, **"biodegradable"**, or similar statements are used unless supported by appropriate evidence.
2. The packaging is not marked with symbols intended for biological waste.
3. 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 box	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

1. 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.
2. 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.
3. 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.
4. For group and transport packaging, the number of packaged units per carton, palletisation and utilisation of transport space are optimised.
5. 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 box	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

1. The sterile barrier system is clearly designated as **single-use packaging**.
2. The packaging is not labelled or marketed as reusable.
3. 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 box	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 box	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

1. A standard packing configuration shall be defined for every group and transport package.
2. The number of sales units per shipping carton shall be optimised to minimise unused internal volume.
3. Cushioning materials shall only be used where necessary to prevent damage during transport.
4. The dimensions of shipping cartons shall be reviewed whenever the product dimensions, packaging configuration or transport conditions change.
5. 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 and Tertiary 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 Article 24(4)	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 Bottle bellows pouch

9.1.1 Packaging Technical Specifications

- Bottle bellows pouch specification
- Bottle bellows pouch I specification
- Canula bellows pouch specification
- Closure bellows pouch specification
- Closure bellows pouch I specification

9.1.2 Packaging Raw Material Specifications

Bellows pouch

- Closure com PHARMALENE.pdf – HDPE Pharmalene MP 90 PH (Versalis)

9.1.3 Product Stewardship documents

They contain technical data, regulatory information and statements from polymer manufacturers. Purell PE 1840H - Product Stewardship Bulletin (2).pdf

- PSRS Riblene 2025_05 (1).pdf

- Regulatory Information Sheet PE UNCOLORED.pdf
- REGULATORY_050012_v092025_PRIMEVA P1340.pdf

9.1.4 EU legislation declaration (Food Contact, PPWR, REACH, BPA)

Documents confirming compliance with European legislation.

- Declaration on Reg. 2025_40_UE and 2024_3190.pdf
- REGULATORY_050012_v092025_PRIMEVA P1340.pdf
- Regulatory Information Sheet PE UNCOLORED.pdf
- Purell PE 1840H - Product Stewardship Bulletin (2).pdf
- PSRS Riblene 2025_05 (1).pdf

9.1.5 PFAS declarations

Documents focused on the absence of PFAS.

- PFAS.pdf
- PFAS e recycle.pdf
- FEBO - no PFAS - Edistir N 3910, R 321P, Eraclene MP 90, Pharmalene BC 82 PH, MP 20 PH, Riblene FC 39 F, MV 10..pdf

9.1.6 BPA / Bisfenoly

Dokumenty vztahující se k nařízení (EU) 2024/3190.

- BISFENOLO BPA.pdf
- Declaration on Reg. 2025_40_UE and 2024_3190.pdf

9.1.7 Documents dealing with recycled material, PPWR and environmental aspects.

- PFAS e recycle.pdf
- Regulatory Information Sheet PE UNCOLORED.pdf
- Declaration on Reg. 2025_40_UE and 2024_3190.pdf

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 Tertiary packaging

9.3.1. Technical Data Sheets

- ARHA Technical Data Sheet
- The roll – Film PA/PE U Standard, peel

9.3.2 Declarations of Compliance

- ARHA Declaration of Compliance (MED_05-2022)
- Prohlášení o shodě – PA/PE_U (verze 2026/245)

9.3.3 Certificates

- ARHA Certificate of Analysis

9.3.4 PPWR statements

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

9.4. Paper box

Packaging Technical Specifications

- Product Safety Statement – ALASKA WHITE / Virgin Fibre Cartonboard (MM BOARD & PAPER)
- Prohlášení dodavatelů k PPWR
- Prohlášení o shodě – Polygra a.s. (PPWR čl. 5 – nebezpečné látky)

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