

EU DECLARATION OF CONFORMITY

Regulation (EU) 2025/40 Packaging and Packaging Waste Regulation

Declaration No.: [1000-DOC-002/ V1]

Applicability date: Regulation (EU) 2025/40 applies from 12 August 2026

1. Unique identification of the packaging and Object of the declaration

Product Name	Model Number	Internal Product code
Patch Insulin Pump system(including Ambulatory Insulin Infusion Pump and Portable Diabetes Assistant)	MTM-1, MTM-I	1001-FMTL-071
Insulin Infusion Set	HRN-S-60 HRN-S-90	1001-FMTL-340 1001-FMTL-412
Insulin Infusion Pump Reservoir	MTM-3 MTM-R10 MTM-3WP MTM-10WP	1001-FMTL-339

2. Manufacturer

Manufacturer: MicroTech Medical (Hangzhou) Co.,Ltd.

Registered address: [No.108 Liuze St., Cangqian, Yuhang District, Hangzhou 311121 Zhejiang P.R.China]

Contact: [IRA@microtechmd.com]

Note: The manufacturer is established outside the European Union (Hangzhou, China). Under the PPWR, the manufacturer has appointed an authorised representative and is registered as a packaging producer under the Extended Producer Responsibility (EPR) scheme in each Member State where the products are placed on the market. The importer is responsible, in accordance with Article 17 of the PPWR, for verifying that this declaration and the accompanying technical documentation are drawn up and kept available.

3. Statement of sole responsibility

This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration (description of the packaging)

The object of this declaration is the complete packaging of every product family placed on the market, namely: Note: The material composition stated above is based on written material declarations provided by each packaging supplier and is recorded in the technical documentation (Annex VII). Where a material is stated as a family (e.g. 'Paper / adhesive / ink'), the individual constituent components are identified in the corresponding supplier declaration and the restriction-substances declarations held in the technical file.

Packaging Item	Supplier	Material (per supplier declaration)	Packaging Level	Product(s)
Shipping Carton	Suzhou Haishun Packaging Materials Co., Ltd.	Corrugated cardboard	Shipping	Pump system
Sales Unit Box	Supplier 1: Hangzhou Hangqian Printing Technology Co., Ltd. / Supplier 2: Hangzhou Datang Printing Co., Ltd.	White/grey board paper	Secondary	Pump system
Pump Carton Inner Cover	Hangzhou Tianwei Packaging Co., Ltd.	White board paper	Secondary	Pump system
IFU Belly Band	Supplier 1: Zhejiang Jinri Printing Co., Ltd. / Supplier 2: Deqing Shuanghe Printing Equipment Co., Ltd.	White board paper	Collective	Pump system
All Labels	Supplier 1: Hangzhou Hangqian Printing Technology Co., Ltd. / Supplier 2: Hangzhou Datang Printing Co., Ltd.	Paper / adhesive / ink	Various levels	Pump system,
Quality Seal Stickers	Hangzhou Huke Label Technology Co., Ltd.	Paper / adhesive	Secondary	Cannula Inserters, Insulin infusion

SN Barcode Label	Supplier 1:Hangzhou Hangqian Printing Technology Co., Ltd. / Supplier 2: Hangzhou Datang Printing Co., Ltd.	Paper / adhesive	Direct	set, Reservoir Pump
PDA Label	Supplier 1:Hangzhou Hangqian Printing Technology Co., Ltd. / Supplier 2: Hangzhou Datang Printing Co., Ltd.	Paper / adhesive	Direct	Pump
Sterile Barrier	MDK (Shanghai) Packaging Material Co., Ltd.	Tyvek / medical grade paper	Direct	Insulin infusion set,Reservoir
EPE Foam	Supplier 1:Hangzhou Tengyue New Material Technology Co., Ltd. / Supplier 2:Hangzhou Chengyi Packaging Materials Co., Ltd.	Expanded Polyethylene (PE)	Shipping	Cannula Inserter
Pump Bubble Bag	Jinhua Xiangyue Packaging Co., Ltd.	Polyethylene (PE)	Shipping	Pump

5. Conformity statement — applicable requirements of Regulation (EU) 2025/40

Conformity statement: The packaging identified in Point 4 is declared to be in conformity with Regulation (EU) 2025/40. The applicability of the essential requirements of Articles 5 to 12 to each packaging item is set out in the matrix below.

PPWR requirement	Subject	Status / basis of conformity
Art. 5 – Substances of concern	Sum of Pb, Cd, Hg, Cr(VI) $\leq$ 100 mg/kg (Art. 5(4)); PFAS	APPLICABLE – third-party heavy-metal testing of each packaging component (ICP-

PPWR requirement	Subject	Status / basis of conformity
	restriction (food-contact only)	MS/AAS; Cr(VI) per EN 1122) + supplier declarations, recorded in TD-Annex B. PFAS: N/A (not food contact).
Art. 6 – Design for recyclability	Recyclability incl. performance grades per delegated act (due by end-2026)	APPLICABLE WITH DEROGATION – contact-sensitive primary packaging (Aluminium Pouch, Sterile Barrier) exempt under Art. 6(11) as MDR contact-sensitive medical-device packaging; review by 2035. All other items designed for recyclability (paper/board), assessed in TD.
Art. 7 – Minimum recycled content	Plastic recycled-content thresholds from 1 Jan 2030	N/A AT PRESENT – contact-sensitive plastic packaging exempt under Art. 7(4); PE bubble bag / EPE foam to be assessed against 2030 thresholds; DOC to be updated accordingly.
Art. 8 – Bio-based content	Only where claimed	N/A – no bio-based claim.
Art. 9 – Compostability	Only where claimed	N/A – not compostable by design.
Art. 10 – Minimisation	Min. necessary weight/volume; empty-space ratio $\leq 50\%$ for grouped/transport/e-commerce packaging from 2030 (Art. 24)	APPLICABLE – dimensions optimised; space-ratio assessment in TD; verify against Art. 24 before 2030.
Arts. 11 & 26–33 – Reuse / refill	Reusable / refillable packaging obligations	N/A – single-use medical-device packaging.
Art. 12 – Harmonised labelling	Material label from 12 Aug 2028; exemption for immediate/outer packaging with no space (Art. 12(11)); transport packaging exempt (Art. 12(1))	N/A AT PRESENT – exemption under Art. 12(11) applies where MDR/IVDR labelling leaves no space or would jeopardise safe use; re-assess before 2028.

6. Harmonised standards, common specifications and other technical specifications

Regulation (EU) 2025/40

Regulation (EC) No 1907/2006 (REACH)

Directive 2011/65/EU (RoHS)

7. Notified body

NOT APPLICABLE. Conformity assessment is performed under Module A (internal production control) pursuant to Article 38 of Regulation (EU) 2025/40; no notified body is involved in the assessment of this packaging. No CE marking is required on the packaging under the PPWR.

8. Place, date and signature

Place of issue: [Hangzhou, China]

Date of issue: [03 September 2026]

Name of signatory: [Xiaojing Zhao]

Function: [RA Supervisor]

Signature: Xiaojing Zhao