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EU DECLARATION OF CONFORMITY FOR PACKAGING

pursuant to Article 39 and Annex VIII of Regulation (EU) 2025/40 on packaging and packaging waste (PPWR)

No. DDC-PPWR-01 – Rev. 00

Subject: Secondary and tertiary packaging of EUROFARM medical devices

Rev.	Date	Description	Editorial Staff	Verification and approval
00	04/08/2026	First issue	QuaSer Srl (Ing. B. Rissone, Ing. P. Rissone)	EUROFARM SpA – Legal Representative

Introduction and regulatory framework

Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904 and repealing Directive 94/62/EC (hereinafter 'PPWR' or 'Regulation'), published in the Official Journal of the European Union, L series, of 22 January 2025, entered into force on 11 February 2025 and applies generally from 12 August 2026. From that date, PPWR repeals and replaces Directive 94/62/EC on packaging and packaging waste and any packaging placed on the Union market must be covered by an EU declaration of conformity drawn up by the manufacturer in accordance with the model set out in Annex VIII to the Regulation.

Pursuant to Article 3, paragraph 1, point 13) of the PPWR, the "manufacturer" is considered not only the person who physically produces the packaging, but also the person who has the packaging designed or manufactured and markets it under their own name or trademark. EUROFARM SpA, a company active since 1979 in the research, production, and distribution of plasters, sterile surgical dressings, bandages, and advanced dressings, with a management system certified according to ISO 9001 and ISO 13485 standards, has the packaging bearing its own brand designed and manufactured by qualified suppliers and places its packaged medical devices on the market. Therefore, for the packaging covered by this declaration, it assumes the role of manufacturer and the related obligations set forth in Article 15 of the Regulation.

In accordance with Article 15, paragraph 2, of the PPWR, before placing the packaging on the market, EUROFARM SpA conducted the conformity assessment according to the procedure referred to in Article 38, corresponding to the internal production control module (Module A) described in Annex VII, and prepared the related technical documentation. This procedure does not require the intervention of a notified body, nor does the PPWR require the affixing of the CE marking to the packaging: conformity is certified by this declaration, supported by the technical documentation referred to in Annex VII, which is

retained together with the declaration for a period of five years from the placing on the market of the single-use packaging, pursuant to Article 15, paragraph 3.

This declaration is continuously updated in accordance with the same Article 39, paragraph 2, and its structure closely follows the eight points of the model in Annex VIII. Commission Communication C/2026/3084, containing the guidance document for Regulation (EU) 2025/40, published in the Official Journal of the European Union on 10 June 2026, was also considered as an interpretative aid.

This declaration covers the secondary (cardboard boxes) and tertiary (corrugated cardboard boxes) packaging of EUROFARM medical devices. The primary packaging, consisting of the sterile barrier system that preserves the sterility of the device until use, is not covered by this declaration and is addressed, with regard to its classification in the PPWR, in section 8.3 below.

1. Number and unique identification of the packaging (Annex VIII, point 1)

Declaration number: DDC-PPWR-01, Rev. 00. The declaration covers the types of packaging identified below, placed on the market by EUROFARM SpA to accompany its medical devices starting from 12 August 2026, the date of application of the Regulation.

Cod.	Packaging type and description	Supplier	Material identification (Dec. 97/129/EC)
S1	Secondary packaging – cardboard box made of pure cellulose (virgin fibre), type «PRO FBB BRIGHT» or equivalent (representative weight 280 g/m²); printing and die-cutting compliant with EUROFARM specifications; single-use.	Eurografica Srl – Catania	PAP 21 – non-corrugated cardboard
S2	Secondary packaging – recycled cardboard box, type «RDM 963» or equivalent (representative weight 400 g/m²), with a declared recycled material content of 90%; printing and die-cutting compliant with EUROFARM specifications; single-use.	Eurografica Srl – Catania	PAP 21 – non-corrugated cardboard
T1	Tertiary packaging – American corrugated cardboard packaging box (HAVANA quality, high or low flute), flexographic printing with water-based inks, declared recycled fiber content of 33%; supplied flat, disposable.	SIFIM Srl – Belpasso (CT)	PAP 20 – corrugated cardboard

Traceability of individual packaging units is ensured by the item code and production batch shown on the identification labels and supplier delivery documents, as well as by the quality control certificates issued for each order. For example: Eurografica quality control certificate no. 20625 of 29/05/2026 (pure cellulose boxes «PRO FBB BRIGHT» 280 g/m², product EURODERM FOAM PLUS 20×20 cm 3 PCS, code 232122, format BN6404, batch K250526/2) and certificate no. 20730 of 06/07/2026 (cases in recycled cardboard «RDM 963» 400 g/m², product EURODERM FOAM PLUS CONCAVE 16.5×18×3, code 232123, format BQ4041, batch K010726/8).

For tertiary packaging (T1), the object codes of the SIFIM Srl supplier declaration are the following:

SIFIM Code	Customer reference EUROFARM	Quality	Internal dimensions (mm)	Weight (g)	Recycling (%)
2165201	296202 – CART. GP PRINT. 550×480×382 mm EUROFARM	HAVANA HIGH WAVE	546 × 476 × 374	990.17	33
2140701	296304 – Anonymous cartoon	HAVANA LOW WAVE	407 × 302 × 209	289.13	33
2140601	296321 – Anonymous cartoon	HAVANA LOW WAVE	407 × 302 × 289	332.19	33

SIFIM Code	Customer reference EUROFARM	Quality	Internal dimensions (mm)	Weight (g)	Recycling (%)
2070001	296302 – Anonymous	HAVANA HIGH WAVE	546 × 476 × 374	990.17	33
2069701	296201 – CART. PP PRINTED. 410×310×270 mm EUROFARM	HAVANA LOW WAVE	407 × 307 × 264	325.33	33
1754201	296218 – CART. PRINTED DD. 565×488×398 mm EUROFARM	HAVANA HIGH WAVE	561 × 484 × 390	1040.06	33

2. Name and address of the manufacturer (Annex VIII, point 2)

Company name	EUROFARM SpA
Registered office and factory	Piano Tavola Industrial Area – 95032 Belpasso (CT) – Italy
VAT number / Tax code	00753720879
Registration in the company register	REA CT-120085
Contacts	Tel. +39 095 391346 – info@eurofarm-spa.com – www.eurofarm-spa.com
Legal Representative	Dr. Lidia Giuseppina Finocchiaro

EUROFARM SpA acts as the manufacturer pursuant to Article 3, paragraph 1, point 13, of the PPWR. The authorised representative referred to in Article 16 of the Regulation is not applicable, as the manufacturer is established in the Union.

3. Sole responsibility of the manufacturer (Annex VIII, point 3)

This declaration of conformity is issued under the exclusive responsibility of the manufacturer EUROFARM SpA. By drawing up this declaration, the manufacturer assumes responsibility for the conformity of the packaging with the applicable requirements established by the Regulation, pursuant to Article 39, paragraph 4, of the PPWR.

4. Subject of the declaration (Annex VIII, point 4)

This declaration covers the secondary and tertiary packaging, identified in point 1 (types S1, S2, and T1), used by EUROFARM SpA to package its medical devices—plasters, sterile surgical dressings, bandages, and advanced line dressings—intended for the hospital and pharmacy channels. In any case, these are single-use packaging items, made entirely of cellulose material, with no plastic components, windows, or bonding with other materials.

The cardboard boxes (S1 and S2) contain the sales units of the device and perform the functions of protection, presentation, and information at the time of purchase; the corrugated cardboard boxes (T1) perform the functions of grouping and transporting the sales units along the distribution chain. For the purposes of correct interpretation of this declaration, it is specified that the terminology used here is the one used in the medical device sector (primary packaging = sterile barrier system; secondary = box; tertiary = transport packaging), while, according to the functional categories of Article 3 of the PPWR, the boxes constitute the sales packaging and the corrugated cardboard boxes constitute the transport packaging.

The gradual transition of cartons from pure cellulose cardboard (S1) to recycled cardboard (S2) is underway: both configurations, intended to coexist during the transition period, are covered by this

declaration, each with respective documentary evidence (see points 5, 8.1, and 8.2). Primary packaging that guarantees the maintenance of product sterility is excluded from the scope of this declaration, as specified in point 8.3.

5. Compliance with relevant Union harmonisation legislation (Annex VIII, point 5)

The object of the declaration referred to in point 4 complies with the relevant Union harmonization legislation: Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste. Conformity is declared with respect to the requirements set out in Articles 5 to 12 of the Regulation, to the extent that they are applicable to the types of packaging covered by the declaration and according to the deadlines established by the Regulation itself, as summarised in the following table.

Requirement – Reg. (EU) 2025/40	Effective date / applicability	Compliance position	Evidence
Art. 5, par. 1–3 Substances in packaging – minimising substances of concern	Applicable from 12/08/2026	Compliant. Cellulose packaging; tertiary packaging printed with water-based flexographic inks; suppliers declare that no substances subject to restrictions under the Regulation are intentionally added in the production of raw materials and packaging, and that BPA is not intentionally added.	Eurografica Declaration 14/07/2026 (S1 and S2), section 3; SIFIM Declaration Rev. 02 of 15/07/2026, items 4 and 8
Art. 5, par. 4 Sum Pb + Cd + Hg + Cr(VI) ≤ 100 mg/kg	Applicable from 12/08/2026 (limit in continuity with art. 11 of Directive 94/62/EC)	Compliant. The sum of the concentrations of lead, cadmium, mercury, and hexavalent chromium present in the packaging and its components does not exceed 100 mg/kg, as declared by suppliers for all types (S1, S2, T1).	Eurografica Declaration 14/07/2026 (S1 and S2), section 3; SIFIM Declaration Rev. 02 of 15/07/2026, point 3
Art. 5, par. 5 PFAS in food contact packaging	Applicable from 12/08/2026 only to packaging intended for contact with food	Not applicable: The packaging covered by this declaration is not intended for food contact. As a precaution, the tertiary packaging supplier has nevertheless planned analytical tests for PFAS and heavy metals. Initial results on substrates containing recycled fibers confirm compliance with the requirement.	SIFIM Declaration Rev. 02 of 15/07/2026, points 2 and 8.a
Art. 6 Recyclable packaging	Design criteria for recycling applicable from 01/01/2030, subject to delegated acts (expected by 01/01/2028); full-scale recycling from 2035. In the meantime, the essential requirements of Annex II of Directive 94/62/EC and the EN 13430 standard are relevant (see Communication C/2026/3084).	Compliant with applicable requirements. Single-material cellulose-based packaging (PAP 20 / PAP 21), designed to be recyclable and declared as such by suppliers; suitable for disposal in the separate waste collection and paper recycling chain.	Eurografica Declaration 14/07/2026, sections 3 and 4 ("recyclable"); SIFIM Declaration, point 5
Articles 7 and 8	From 01/01/2030, or from the subsequent	Not applicable: the packaging covered by the declaration does not	Eurografica Recycled

Requirement – Reg. (EU) 2025/40	Effective date / applicability	Compliance position	Evidence
Minimum recycled content and bio-based raw materials in plastic packaging	date determined by the implementing act referred to in Article 7; requirements relating to plastic packaging	contain plastic components. Voluntary environmental information includes the declared recycled fibre content: 90% for recycled cardboard (S2) and 33% for corrugated cardboard (T1).	Declaration 14/07/2026, section 4; SIFIM Declaration, attached list
Art. 9 Compostable packaging	According to the deadlines set out therein, only for the formats indicated in the article	Not applicable: The types of packaging covered by the declaration are not among the formats for which Article 9 requires compostability.	—
Art. 10 Minimizing packaging	Applicable from 01/01/2030; in the meantime, the EN 13428:2004 standard applies (see Communication C/2026/3084)	Compliant with applicable requirements. Packaging is designed and manufactured based on technical specifications, drawings, and specifications defined by EUROFARM, with dimensions and weights commensurate with the protection, handling, transportation, and presentation functions of the devices, without elements intended solely to increase the perceived bulk of the product.	SIFIM Declaration, item 6; Eurografica quality control certificates no. 20791 and no. 20730
Art. 11 Reusable packaging	Requirements applicable to packaging placed on the market as reusable	Not applicable: The packaging covered by the declaration is disposable and is not marketed as reusable. The supplier of the tertiary packaging leaves any reusability assessment to the user, as the product is supplied flat and not formed.	SIFIM Declaration, point 7
Art. 12 Packaging labelling	Harmonized labelling applicable from 12/08/2028, subject to the relevant implementing acts	Compliant with applicable requirements. Currently, packaging is identified according to the system established in Decision 97/129/EC (PAP 21 for cases; PAP 20 for corrugated cardboard), in accordance with national environmental labeling requirements pursuant to Legislative Decree 116/2020; tertiary packaging is also accompanied by an identification label containing the supplier's details.	Dec. Eurografica, sec. 2; Dec. SIFIM, point 9

6. References to the harmonised standards or other technical specifications applied (Annex VIII, point 6)

As of the date of issue of this declaration, no references to harmonized standards have been published in the Official Journal of the European Union, nor have any common specifications been adopted pursuant to Regulation (EU) 2025/40. Conformity is therefore declared with reference to the following technical

specifications, applied voluntarily as state of the art, as well as to the interpretative guidelines of the European Commission:

- **EN 13427:2004**(UNI EN 13427) – Packaging: requirements for the use of European standards in the field of packaging and packaging waste;
- **EN 13428:2004**(UNI EN 13428) – Packaging: specific requirements for manufacturing and composition – prevention by source reduction, applicable for the purposes of art. 10 of the PPWR until 1 January 2030, as clarified by Communication C/2026/3084;
- **EN 13430:2004**(UNI EN 13430) – Packaging: requirements for packaging recoverable through material recycling, as a reference for recyclability pending the adoption of the delegated acts referred to in art. 6 of the PPWR;
- **Decision 97/129/EC**of the Commission, establishing a system for the identification of packaging materials (codes PAP 20 – corrugated cardboard and PAP 21 – non-corrugated cardboard);
- **Communication from the Commission C/2026/3084**– Guidance document for Regulation (EU) 2025/40 on packaging and packaging waste (OJEU of 10 June 2026).

The tertiary packaging supplier also refers, in its declaration, to UNI EN 13427 as a general reference and to the DIN 55429 standard for the dimensional profiles of corrugated cardboard boxes.

7. Notified body (Annex VIII, point 7)

Not applicable. The conformity assessment of the packaging was conducted according to the internal production control procedure (Module A) referred to in Article 38 and Annex VII of Regulation (EU) 2025/40, which does not require the involvement of a notified body or the issuance of certificates by third parties.

8. Additional information (Annex VIII, point 8)

8.1 Documentary evidence from suppliers

This declaration is based not only on EUROFARM SpA's technical purchasing specifications and acceptance checks, but also on the declarations and certificates issued by packaging suppliers, contained in the technical documentation in Annex VII. Eurografica Srl operates under an ISO 9001 (DNV) certified quality management system.

Document	Issuer	Date / Rev.	Relevant content
Declaration of conformity for packaging pursuant to Regulation (EU) 2025/40 – PPWR (pure cellulose cardboard)	Eurografica Srl – Industrial Area, Terza Strada 20/22, 95121 Catania – VAT No. 02434010878	Catania, July 14, 2026 – signed by G. Capuano (RQA)	Material: cardboard, PAP code 21; compliance with material composition and identification, management and recovery, restriction of hazardous substances, and design for recyclability; heavy metals (Pb, Cd, Hg, Cr VI) total < 100 mg/kg; packaging declared recyclable.
Declaration of conformity for packaging pursuant to Regulation (EU) 2025/40 – PPWR (recycled cardboard)	Eurografica Srl	Catania, July 14, 2026 – signed by G. Capuano (RQA)	Contents as above; declared recycled content: 90%; packaging declared recyclable.
Quality Control Certificate No. 20625	Eurografica Srl	July 27, 2026	"PRO FBB BRIGHT" pure cellulose cardboard boxes, 280 g/m², thickness 0.485 mm; product EURODERM FOAM PLUS 20×20 cm 3 PCS, code 232122, format

Document	Issuer	Date / Rev.	Relevant content
			g/m², thickness 0.485 mm; product EURODERM FOAM PLUS 20×20 cm 3 PCS, code 232122, format BN6404, batch K250526/1; compliant test results.
Quality Control Certificate No. 20730	Eurografica Srl	06/07/2026	Recycled cardboard boxes «RDM 963», 400 g/m², thickness 0.525 mm; product EURODERM FOAM PLUS CONCAVE 16.5×18×3, code 232123, format BQ4041, batch K010726/8; compliant test results.
Declaration «EUROFARM SPA_PPWR SFM Dich 02 260715» – compliance with Reg. (EU) 2025/40 of the corrugated cardboard packaging supplied	SIFIM Srl – C.da Pantano snc, Loc. Valcorrente, 95032 Belpasso (CT) – VAT No. 04752740870	Rev. 02 of 07/15/2026 – signed Y. Napoli (Quality Manager)	American corrugated cardboard boxes, flexographic printing with water-based inks; classified as packaging pursuant to Article 3 of the PPWR; heavy metals ≤ 100 mg/kg; PFAS not applicable (non-food packaging) with precautionary analytical investigations underway; BPA unintentionally added; recyclable packaging pursuant to Article 6; minimization according to customer specifications; list of codes supplied with 33% recycled content; commitment to communicate any significant changes.

8.2 Transition from pure cellulose cardboard to recycled cardboard

The progressive replacement of pure cellulose cardboard (S1) with recycled cardboard (S2) for packaging is underway, in line with the circularity objectives pursued by the Regulation. During the transitional period, the two configurations will coexist and are both covered by this declaration, each supported by the respective evidence referred to in point 8.1. Any changes to the design or characteristics of the packaging, or to the reference technical specifications, that may impact compliance will require a repeat of the assessment pursuant to Article 15, paragraph 4, and the consequent updating of this declaration pursuant to Article 39, paragraph 2, of the PPWR.

8.3 Primary packaging (sterile barrier system)

The primary packaging of EUROFARM medical devices, consisting of the sterile barrier system that maintains the sterility of the product until use, is not covered by this declaration. Pursuant to Article 3, paragraph 1, of the PPWR, this packaging qualifies as "contact-sensitive packaging" as it is intended for products covered by Regulation (EU) 2017/745 on medical devices. The Regulation provides for specific exemptions for such packaging: specifically, Article 6 (recyclable packaging) does not apply to contact-sensitive packaging for medical devices, pursuant to Article 6, paragraph 11, letter b), and Article 7 provides specific exemptions from the recycled content requirements for contact-sensitive plastic packaging for the same devices.

For primary packaging, the general requirements applicable to all packaging remain in place, particularly Article 5 regarding substances: the collection of relevant evidence from suppliers of primary packaging materials is the subject of a separate qualification process, the results of which are documented in the technical documentation referred to in Annex VII. The functional suitability of the sterile barrier system is,

in any case, already qualified and documented in the technical file for the devices pursuant to Regulation (EU) 2017/745, Annex I, and the EN ISO 11607 series.

8.4 Storage, updating and provision

This declaration and the technical documentation referred to in Annex VII are retained by EUROFARM SpA for five years after the single-use packaging is placed on the market, pursuant to Article 15, paragraph 3, of the PPWR, and are made available to market surveillance authorities upon request. The declaration is continuously updated pursuant to Article 39, paragraph 2; suppliers have undertaken to promptly communicate any changes to packaging components, production processes, or the supply chain that may potentially impact compliance.

Signed for and on behalf of: EUROFARM SpA

Belpasso (CT), there 05/08/2026

Dr. Giuseppina Lidia Finocchiaro
Legal Representative

Signature: _____

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