

BATIST Medical a.s.
EU DECLARATION OF CONFORMITY/EU PROHLÁŠENÍ O SHODĚ
Packaging and Packaging Waste Regulation (EU) 2025/40 (PPWR) Article 39 and Annex VIII

EU Declaration of Conformity No./ EU Prohlášení o shodě č.	BM_PPWR-DOC-010
Revision/Revize/Date/Datum	01/ 21.08.2026

1. Unique identification of the packaging/ Jedinečná identifikace obalu

Packaging associated with Medical Device REF(s)/Obal související se zdravotnickými prostředky s následujícími REF:

1320100510I, 1320100520I, 1320100530I, 1320100540I, 1320100629, 1326004117, 1326002661, 1326002662, 1326002663, 1326002664, 1326002665

The packaging covered by this Declaration is uniquely identified through the applicable Medical Device REF(s) in combination with the corresponding Bill of Materials (BOM), packaging specification(s) and/or packaging component identification maintained by the manufacturer, see Annex 1.

Obal, na který se vztahuje toto prohlášení, je jednoznačně identifikován prostřednictvím příslušných REF zdravotnických prostředků ve spojení s odpovídajícím kusovníkem (BOM), specifikací obalu a/nebo identifikací obalových komponent vedenou výrobcem

2. Manufacturer/Výrobce

BATIST Medical a.s.
Nerudova 744
549 41 Červený Kostelec
Czech Republic

3. Responsibility of the manufacturer/Odpovědnost výrobce

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Toto EU prohlášení o shodě je vydáváno na výhradní odpovědnost výrobce.

4. Object of the declaration/Předmět prohlášení

The object of this Declaration is the packaging associated with the medical device(s) identified in Section 1 and in Annex 1, where applicable. The packaging components are defined and controlled through the applicable BOM, approved packaging specifications and PPWR technical documentation.

Předmětem tohoto prohlášení je obal související se zdravotnickým prostředkem (prostředky) identifikovaným(i) v oddílu 1 a v příloze 1. Obalové komponenty jsou definovány a řízeny prostřednictvím příslušného kusovníku (BOM), schválených specifikací obalu a technické dokumentace podle PPWR.

The identification system ensures traceability between the Medical Device REF, applicable BOM and the individual packaging specifications/components.

Použitý systém identifikace zajišťuje sledovatelnost mezi REF zdravotnického prostředku, příslušným kusovníkem (BOM) a jednotlivými specifikacemi a komponentami obalu.

5. Applicable Union legislation/Použitelné právní předpisy Evropské unie

The packaging identified above is in conformity with the applicable requirements of Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste (PPWR), including the applicable requirements laid down in or pursuant to Articles 5 to 12.

Výše identifikovaný obal je ve shodě s příslušnými požadavky nařízení Evropského parlamentu a Rady (EU) 2025/40 ze dne 19. prosince 2024 o obalech a obalových odpadech (PPWR), včetně požadavků stanovených v článcích 5 až 12 nebo přijatých na jejich základě.

Medical-device specific provisions / derogations. Where a PPWR derogation or specific provision applies to packaging used for a medical device, including a sterile barrier system or other safety-critical packaging, the applicability and justification are documented in the PPWR Technical Documentation. No general precedence of MDR over PPWR is claimed by this Declaration.

Zvláštní ustanovení a výjimky pro zdravotnické prostředky. Pokud se na obal zdravotnického prostředku, včetně sterilního bariérového systému nebo jiného bezpečnostně kritického obalu, vztahuje zvláštní ustanovení nebo výjimka podle PPWR, jsou jejich použitelnost a odůvodnění zdokumentovány v technické dokumentaci PPWR. Tímto prohlášením není uplatňována žádná obecná přednost nařízení (EU) 2017/745 (MDR) před nařízením (EU) 2025/40 (PPWR).

6. Standards, Technical Specifications and Supporting Documentation/Normy, Technická specifikace a podpůrná dokumentace

The conformity assessment is supported by applicable standards, technical specifications and supporting documentation maintained under the manufacturer's Quality Management System.

Posouzení shody je podloženo příslušnými normami, technickými specifikacemi a podpůrnou dokumentací vedenou v rámci systému řízení kvality výrobce

Supporting evidence includes, where applicable: applicable European and international standards; approved Bill(s) of Materials (BOM); approved Packaging Specifications; material specifications; supplier declarations and certificates; REACH and SVHC declarations, where applicable; declarations regarding recycled content and recyclability, where applicable; technical reports and test reports; internal PPWR compliance assessments.

Podpůrné důkazy zahrnují zejména: příslušné evropské a mezinárodní normy; schválené kusovníky (BOM); schválené specifikace obalů; specifikace materiálů; prohlášení a certifikáty dodavatelů; prohlášení týkající se REACH a SVHC, pokud jsou relevantní; prohlášení o obsahu recyklovaného materiálu a recyklovatelnosti, pokud jsou relevantní; technické zprávy a protokoly o zkouškách; interní posouzení shody s požadavky PPWR.

The detailed evidence demonstrating conformity is maintained in the applicable PPWR Technical Documentation established in accordance with Annex VII of Regulation (EU) 2025/40.

Podrobné důkazy prokazující shodu jsou uchovávány v příslušné technické dokumentaci PPWR vypracované v souladu s přílohou VII nařízení (EU) 2025/40.

7. Notified body/Notifikovaná osoba

Not applicable, unless notified body involvement is required under applicable Union legislation.



Nevztahuje se, pokud příslušné právní předpisy Evropské unie nevyžadují zapojení notifikované osoby.

8. Additional information/Doplňující informace

The conformity assessment has been performed in accordance with Article 38 and Annex VII of Regulation (EU) 2025/40. Supporting technical documentation includes, as applicable, packaging specifications and drawings, BOM, material composition, supplier documentation, information on substances of concern, recyclability assessment, recycled content information, test reports/certificates and evidence supporting compliance with the applicable requirements of Articles 5–12.

Posouzení shody bylo provedeno v souladu s článkem 38 a přílohou VII nařízení (EU) 2025/40. Podpůrná technická dokumentace zahrnuje podle potřeby zejména: specifikace a výkresy obalů; kusovníky (BOM); složení materiálů; dokumentaci dodavatelů; informace o látkách vzbuzujících obavy (Substances of Concern – SoC); posouzení recyklovatelnosti; informace o obsahu recyklovaného materiálu; protokoly o zkouškách a certifikáty; důkazy prokazující splnění příslušných požadavků článků 5 až 12.

This Declaration shall be reviewed and updated where changes to packaging design, material composition, supplier, applicable legislation, standards or technical specifications may affect conformity.

Toto prohlášení musí být přezkoumáno a v případě potřeby aktualizováno při změně konstrukce obalu, složení materiálu, dodavatele, příslušných právních předpisů, norem nebo technických specifikací, které mohou ovlivnit shodu.

Signature/Podpis

Signed for and on behalf of/Podepsáno za	BATIST Medical a.s.
Place and date of issue/Místo a datum vydání	Červený Kostelec
Name/Jméno	Věra Valešová
Function/Funkce	Regulatory Affairs Manager
Signature/Podpis	



Annex 1_LIST OF MEDICAL DEVICE REFs AND PACKAGING IDENTIFICATION

This Annex forms an integral part of EU Declaration of Conformity No. BM-PPWR-DOC-010.

REF	Packaging Material	Composition	Sterile or not
1320100510I	Wrapping Pape	100% unbleached virgin softwood sulphite pulp, internal starch sizing agent, minor mineral fillers, water-based dye (for coloured variants) or uncoloured natural stock. No plastic coating, lamination, wax, PFAS or plastic components. All printing adopts water-based ink only. Material code: 21 PAP.	Non-sterile
	Paper Pallet Divider Board	Solid cardboard spacer board composed of recycled paper fibre, starch sizing agent, without plastic layers; printed with water-based ink if applicable, material code 21 PAP.	
	Label-Self-adhesive label	Fabric: cellulose, calcium carbonate, water; Adhesive: SIS rubber, petroleum resin, naphthenic oil; Base paper: cellulose polymethylvinylsiloxane	
	Printing ink	C.I. Pigment Violet 27; 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, 2-(2-ethoxyethoxy)ethyl ester; ammonia; 2,4,7,9-tetramethyldec-5-yne-4,7-diol	
	PE bag	Polyethylene	
	Carton-5 layers yellow cardboard box without printing	Cellulosepulp, water, starch, polyacrylamide, styrene/acrylamide copolymer, water-based acrylic resin, pigment, polyvinyl alcohol, vinyl acetate copolymer, Fe, Cu	
	Packing tape	Main substance: polypropylene	
1320100520I	Wrapping Pape	100% unbleached virgin softwood sulphite pulp, internal starch sizing agent, minor mineral fillers, water-based dye (for coloured variants) or uncoloured natural stock. No plastic coating, lamination, wax, PFAS or plastic components. All printing adopts water-based ink only. Material code: 21 PAP.	Non-sterile
	Paper Pallet Divider Board	Solid cardboard spacer board composed of recycled paper fibre, starch sizing agent, without plastic layers; printed with water-based ink if applicable, material code 21 PAP.	

	Label-Self-adhesive label	Fabric: cellulose, calcium carbonate, water; Adhesive: SIS rubber, petroleum resin, naphthenic oil; Base paper: cellulose polymethylvinylsiloxane
	Printing ink	C.I. Pigment Violet 27; 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, 2-(2-ethoxyethoxy)ethyl ester; ammonia; 2,4,7,9-tetramethyldec-5-yne-4,7-diol
	PE bag	Polyethylene
	Carton-5 layers yellow cardboard box without printing	Cellulosepulp, water, starch, polyacrylamide, styrene/acrylamide copolymer, water-based acrylic resin, pigment, polyvinyl alcohol, vinyl acetate copolymer, Fe, Cu
	Packing tape	Main substance: polypropylene
1320100530I	Wrapping Pape	100% unbleached virgin softwood sulphite pulp, internal starch sizing agent, minor mineral fillers, water-based dye (for coloured variants) or uncoloured natural stock. No plastic coating, lamination, wax, PFAS or plastic components. All printing adopts water-based ink only. Material code: 21 PAP.
	Paper Pallet Divider Board	Solid cardboard spacer board composed of recycled paper fibre, starch sizing agent, without plastic layers; printed with water-based ink if applicable, material code 21 PAP.
	Label-Self-adhesive label	Fabric: cellulose, calcium carbonate, water; Adhesive: SIS rubber, petroleum resin, naphthenic oil; Base paper: cellulose polymethylvinylsiloxane
	Printing ink	C.I. Pigment Violet 27; 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, 2-(2-ethoxyethoxy)ethyl ester; ammonia; 2,4,7,9-tetramethyldec-5-yne-4,7-diol
	PE bag	Polyethylene
	Carton-5 layers yellow cardboard box without printing	Cellulosepulp, water, starch, polyacrylamide, styrene/acrylamide copolymer, water-based acrylic resin, pigment, polyvinyl alcohol, vinyl acetate copolymer, Fe, Cu
	Packing tape	Main substance: polypropylene
1320100540I	Wrapping Pape	100% unbleached virgin softwood sulphite pulp, internal starch sizing agent, minor mineral fillers, water-based dye (for coloured variants) or uncoloured natural stock. No plastic coating, lamination, wax, PFAS or plastic components. All printing adopts water-based ink only. Material code: 21 PAP.



	Paper Pallet Divider Board	Solid cardboard spacer board composed of recycled paper fibre, starch sizing agent, without plastic layers; printed with water-based ink if applicable, material code 21 PAP.
	Label-Self-adhesive label	Fabric: cellulose, calcium carbonate, water; Adhesive: SIS rubber, petroleum resin, naphthenic oil; Base paper: cellulose polymethylvinylsiloxane
	Printing ink	C.I. Pigment Violet 27; 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, 2-(2-ethoxyethoxy)ethyl ester; ammonia; 2,4,7,9-tetramethyldec-5-yne-4,7-diol
	PE bag	Polyethylene
	Carton-5 layers yellow cardboard box without printing	Cellulosepulp, water, starch, polyacrylamide, styrene/acrylamide copolymer, water-based acrylic resin, pigment, polyvinyl alcohol, vinyl acetate copolymer, Fe, Cu
	Packing tape	Main substance: polypropylene
1320100629	Inner Box	Folding boxboard inner carton, base material is solid paperboard mixed with recycled paper fibre and virgin wood pulp, internal starch sizing agent, no plastic lamination, plastic coating or wax. Attached paper label printed with water-based ink only. All paper substrate and printing ink comply with PPWR heavy metal requirement sum Pb+Cd+Hg+Cr(VI) ≤100 mg/kg. Material identification code: 21 PAP.
	Printing ink	C.I. Pigment Violet 27; 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, 2-(2-ethoxyethoxy)ethyl ester; ammonia; 2,4,7,9-tetramethyldec-5-yne-4,7-diol
	Carton-5 layers yellow cardboard box without printing	Cellulosepulp, water, starch, polyacrylamide, styrene/acrylamide copolymer, water-based acrylic resin, pigment, polyvinyl alcohol, vinyl acetate copolymer, Fe, Cu
	Label-Self-adhesive label	Fabric: cellulose, calcium carbonate, water; Adhesive: SIS rubber, petroleum resin, naphthenic oil; Base paper: cellulose polymethylvinylsiloxane
	Packing tape	Main substance: polypropylene
1326004117	PE bag	Polyethylene

	Product Qualification Certificate Paper Label	Thin paper certificate label attached inside primary packaging, used as product qualification mark, auxiliary packaging component discarded after unpacking. Base material: uncoated printing paper made of mixed recycled fibre and virgin wood pulp with starch sizing agent, plastic-free without lamination or coating. All printing adopts water-based ink only. Material identification code 21 PAP.	
	Carton-5 layers yellow cardboard box without printing	Cellulosepulp, water, starch, polyacrylamide, styrene/acrylamide copolymer, water-based acrylic resin, pigment, polyvinyl alcohol, vinyl acetate copolymer, Fe, Cu	
	Label-Self-adhesive label	Fabric: cellulose, calcium carbonate, water; Adhesive: SIS rubber, petroleum resin, naphthenic oil; Base paper: cellulose polymethylvinylsiloxane	
	Printing ink	C.I. Pigment Violet 27; 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, 2-(2-ethoxyethoxy)ethyl ester; ammonia; 2,4,7,9-tetramethyldec-5-yne-4,7-diol	
	Packing tape	Main substance: polypropylene	
1326002661	PE bag	Polyethylene	EO Sterile
	Product Qualification Certificate Paper Label	Thin paper certificate label attached inside primary packaging, used as product qualification mark, auxiliary packaging component discarded after unpacking. Base material: uncoated printing paper made of mixed recycled fibre and virgin wood pulp with starch sizing agent, plastic-free without lamination or coating. All printing adopts water-based ink only. Material identification code 21 PAP.	
	Label-Self-adhesive label	Fabric: cellulose, calcium carbonate, water; Adhesive: SIS rubber, petroleum resin, naphthenic oil; Base paper: cellulose polymethylvinylsiloxane	
	Carton-5 layers yellow cardboard box without printing	Cellulosepulp, water, starch, polyacrylamide, styrene/acrylamide copolymer, water-based acrylic resin, pigment, polyvinyl alcohol, vinyl acetate copolymer, Fe, Cu	
	Printing ink	C.I. Pigment Violet 27; 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, 2-(2-ethoxyethoxy)ethyl ester; ammonia; 2,4,7,9-tetramethyldec-5-yne-4,7-diol	
	Packing tape	Main substance: polypropylene	

1326002662	PE bag	Polyethylene
	Product Qualification Certificate Paper Label	Thin paper certificate label attached inside primary packaging, used as product qualification mark, auxiliary packaging component discarded after unpacking. Base material: uncoated printing paper made of mixed recycled fibre and virgin wood pulp with starch sizing agent, plastic-free without lamination or coating. All printing adopts water-based ink only. Material identification code 21 PAP.
	Label-Self-adhesive label	Fabric: cellulose, calcium carbonate, water; Adhesive: SIS rubber, petroleum resin, naphthenic oil; Base paper: cellulose polymethylvinylsiloxane
	Carton-5 layers yellow cardboard box without printing	Cellulosepulp, water, starch, polyacrylamide, styrene/acrylamide copolymer, water-based acrylic resin, pigment, polyvinyl alcohol, vinyl acetate copolymer, Fe, Cu
	Printing ink	C.I. Pigment Violet 27; 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, 2-(2-ethoxyethoxy)ethyl ester; ammonia; 2,4,7,9-tetramethyldec-5-yne-4,7-diol
	Packing tape	Main substance: polypropylene
1326002663	PE bag	Polyethylene
	Product Qualification Certificate Paper Label	Thin paper certificate label attached inside primary packaging, used as product qualification mark, auxiliary packaging component discarded after unpacking. Base material: uncoated printing paper made of mixed recycled fibre and virgin wood pulp with starch sizing agent, plastic-free without lamination or coating. All printing adopts water-based ink only. Material identification code 21 PAP.
	Label-Self-adhesive label	Fabric: cellulose, calcium carbonate, water; Adhesive: SIS rubber, petroleum resin, naphthenic oil; Base paper: cellulose polymethylvinylsiloxane
	Carton-5 layers yellow cardboard box without printing	Cellulosepulp, water, starch, polyacrylamide, styrene/acrylamide copolymer, water-based acrylic resin, pigment, polyvinyl alcohol, vinyl acetate copolymer, Fe, Cu
	Printing ink	C.I. Pigment Violet 27; 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, 2-(2-ethoxyethoxy)ethyl ester; ammonia; 2,4,7,9-tetramethyldec-5-yne-4,7-diol

	Packing tape	Main substance: polypropylene
1326002664	PE bag	Polyethylene
	Product Qualification Certificate Paper Label	Thin paper certificate label attached inside primary packaging, used as product qualification mark, auxiliary packaging component discarded after unpacking. Base material: uncoated printing paper made of mixed recycled fibre and virgin wood pulp with starch sizing agent, plastic-free without lamination or coating. All printing adopts water-based ink only. Material identification code 21 PAP.
	Label-Self-adhesive label	Fabric: cellulose, calcium carbonate, water; Adhesive: SIS rubber, petroleum resin, naphthenic oil; Base paper: cellulose polymethylvinylsiloxane
	Carton-5 layers yellow cardboard box without printing	Cellulosepulp, water, starch, polyacrylamide, styrene/acrylamide copolymer, water-based acrylic resin, pigment, polyvinyl alcohol, vinyl acetate copolymer, Fe, Cu
	Printing ink	C.I. Pigment Violet 27; 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, 2-(2-ethoxyethoxy)ethyl ester; ammonia; 2,4,7,9-tetramethyldec-5-yne-4,7-diol
	Packing tape	Main substance: polypropylene
1326002665	PE bag	Polyethylene
	Product Qualification Certificate Paper Label	Thin paper certificate label attached inside primary packaging, used as product qualification mark, auxiliary packaging component discarded after unpacking. Base material: uncoated printing paper made of mixed recycled fibre and virgin wood pulp with starch sizing agent, plastic-free without lamination or coating. All printing adopts water-based ink only. Material identification code 21 PAP.
	Label-Self-adhesive label	Fabric: cellulose, calcium carbonate, water; Adhesive: SIS rubber, petroleum resin, naphthenic oil; Base paper: cellulose polymethylvinylsiloxane
	Carton-5 layers yellow cardboard box without printing	Cellulosepulp, water, starch, polyacrylamide, styrene/acrylamide copolymer, water-based acrylic resin, pigment, polyvinyl alcohol, vinyl acetate copolymer, Fe, Cu

	Printing ink	C.I. Pigment Violet 27; 2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl) benzene, 2-(2-ethoxyethoxy)ethyl ester; ammonia; 2,4,7,9-tetramethyldec-5-yne-4,7-diol	
	Packing tape	Main substance: polypropylene	