

DoC2025/40PFL1A00

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Manufacturer:

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Model Template:

Annex VIII, Regulation (EU) 2025/40 on packaging and packaging waste (Article 39).

1. Packaging Identification

Refer to Annex 1.

2. Object of declaration:

We hereby declare that the packaging covered by this declaration is in conformity with the relevant Union harmonisation legislation and standards:

Regulation (EU) 2025/40 on packaging and packaging waste
Regulation (EC) No 1907/2006 - REACH

The present declaration of conformity is issued under the sole responsibility of the manufacturer. This declaration is based on the technical information available as of the date of its issuance and may be revised in the event of changes to applicable legislation, the raw materials used, or the information provided by suppliers.

This declaration and the technical documentation will be retained for 5 years.

3. Requirements of Regulation (EU) 2025/40

Article	Requirement	Compliant
5.	Requirements for substances in packaging	Yes
6.	Recyclable packaging	N/A ³
7.	Minimum recycled content in plastic packaging	N/A ³
8.	Biobased feedstock in plastic packaging	N/A
9.	Compostable packaging	N/A
10.	Packaging minimization	In progress ¹
11.	Reusable packaging	N/A
12.	Labelling of packaging	In progress ²

¹ Transitional period;

² Pending implementing act;

³ Contact- sensitive packaging of medical devices covered by regulation EU 2017/745 shall not apply article 6 and 7 of PPWR regulation.

Annex 1

The packaging units that fall under this DoC are:

Packaged Product	Unique Packaging Identification	Packaging Type	Packaging description
3040002 Syringe Water, Luer, 10 ml - Bulk pack *S	05608120025641	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable
3040008 Syringe Water with Glycerine 10%, Luer, 10 ml - Bulk pack *S	05608120025207	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable
3040010 Syringe Water with Glycerine 10%, Luer, 10 ml *S	05608120034056	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable
3020002 Syringe luer lock 5 ml filled with 3 ml NaCl 0,9% sterile	05608120025115	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable
3020010 Syringe luer lock 10 ml NaCl 0,9% sterile	05608120025016	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable
3020008 Syringe luer lock 10 ml filled with 5 ml NaCl 0,9% sterile	05608120025146	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable
3020006 Syringe Water with NaCl 0,9%, Luer Lock, 5 ml - filling 5 ml *S	05608120025139	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable

Packaged Product	Unique Packaging Identification	Packaging Type	Packaging description
3020012 Syringe luer lock 20 ml NaCl 0,9% sterile	05608120025153	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable
3020004 Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - filling 3 ml *S	05608120025122	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable
3010002 Syringe Water with NaCl 0,9%, Luer Lock, 5 ml - filling 3 ml *S inside only	05608120025054	Sales packaging Plastic Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Bioriented Polypropylene film Dimensions: 235*49mm Weight: 0,82g 100% Recyclable
3010010 Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - filling 10 ml *S inside only	05608120025092	Sales packaging Plastic Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Bioriented Polypropylene film Dimensions: 235*49mm Weight: 0,82g 100% Recyclable
3010008 Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - filling 5 ml *S inside only	05608120025085	Sales packaging Plastic Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Bioriented Polypropylene film Dimensions: 235*49mm Weight: 0,82g 100% Recyclable
3010006 Syringe Water with NaCl 0,9%, Luer Lock, 5 ml - filling 5 ml *S inside only	05608120025078	Sales packaging Plastic Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Bioriented Polypropylene film Dimensions: 235*49mm Weight: 0,82g 100% Recyclable
3010012 Syringe Water with NaCl 0,9%, Luer Lock, 20 ml - filling 20 ml *S inside only	05608120025108	Sales packaging Plastic Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Bioriented Polypropylene film Dimensions: 235*49mm Weight: 0,82g 100% Recyclable
3010004 Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - filling 3 ml *S inside only	05608120025061	Sales packaging Plastic Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Bioriented Polypropylene film Dimensions: 235*49mm Weight: 0,82g 100% Recyclable
3990105 Syringe NaCl 0,9% Luer Lock, 5 ml *S inside only	05608120026518	Sales packaging Plastic Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Bioriented Polypropylene film Dimensions: 235*49mm Weight: 0,82g 100% Recyclable

Packaged Product	Unique Packaging Identification	Packaging Type	Packaging description
3990110 Syringe NaCl 0,9% Luer Lock, 10 ml *S inside only	05608120025603	Sales packaging Plastic Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Bioriented Polypropylene film Dimensions: 235*49mm Weight: 0,82g 100% Recyclable
3990115 Syringe NaCl 0,9% Luer Lock, 20 ml *S inside only	05608120026525	Sales packaging Plastic Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Bioriented Polypropylene film Dimensions: 235*49mm Weight: 0,82g 100% Recyclable
3990120 Syringe NaCl 0,9% Luer Lock, 10 ml - 3ml filling *S inside only	05608120026532	Sales packaging Plastic Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Bioriented Polypropylene film Dimensions: 235*49mm Weight: 0,82g 100% Recyclable
3990125 Syringe NaCl 0,9% Luer Lock, 10 ml - 5ml filling *S inside only	05608120026549	Sales packaging Plastic Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Bioriented Polypropylene film Dimensions: 235*49mm Weight: 0,82g 100% Recyclable
3990203 Syringe NaCl 0,9% Luer Lock, 10 ml - 3ml filling *S	05608120026495	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable
3990205 Syringe NaCl 0,9% Luer Lock, 5 ml *S	05608120026471	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable
3990210 Syringe NaCl 0,9% Luer Lock, 10 ml *S	05608120025597	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable
3990220 Syringe NaCl 0,9% Luer Lock, 20 ml *S	05608120026488	Sales packaging Peel Pouch	Function: Sales unit protection (contact sensitive packaging) Materials: Paper Layer and PA/PE layer Dimensions: 220*49mm Weight: 1,33g (Paper: 0,63g ; PA/PE layer 0,7g) Percentage by weight of the functional unit of packaging available for recycling: 0% Not recyclable

Signature:

Joana Pereira

Name:

Joana Pereira

Function:

Management representative

Place and Date:

Penafiel, 14-08-2026