

Appendix 1 Applicant's declaration

For the requirements O1 and O8

Trade name of the product(s): _____

Type of product:

Blood bag

Intravenous (IV) infusion treatment

Peritoneal dialysis treatment

Treatment of urinary retention and incontinence

Ostomy pouches and accessories for treatment
following ileostomy, colostomy or ureterostomy surgery

Description of the product

Parts of the product	Function	Weight of part (g)*	Manufacturer (if external)	Legislation**
				<input type="checkbox"/> Medicinal product <input type="checkbox"/> Medical device
				<input type="checkbox"/> Medicinal product <input type="checkbox"/> Medical device
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* Approximate weight in grams.

** The implementation of the EU Medicinal Products Directive (2001/83/EC) and the Regulation (EU) on Medical Devices (2017/745), with subsequent amendments and adaptations.

O8 Safety

Are the product and/or parts according to the EU Medicinal Products Directive (2001/83/EC) and/or the EU Medical Devices Regulation (2017/745) with subsequent amendments and adaptations. Yes No

Please attach:

- Medical device: Copy of the approval/certificate from a notified body.
- Medicinal product: Copy of the market authorisation from the reference member state or national authority.

Signature

Date and place:	Name of the company:
Responsible person:	Signature of responsible person: