

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: