EU Declaration of Conformity

Manufacturer Name:	Ontex BV
Manufacturer Address:	Genthof 5, 9255 Buggenhout, Belgium
SRN (Single Registration Number):	BE-MF-000003544
Basic UDI-DI:	5414874UnderpadsUU
Product Name:	Underpads
Product Code:	See attached list
Intended Purpose:	The intended purpose of the Underpads is to be placed on a surface and/or underneath a patient to absorb urine and or faeces, as a protection sheet. The devices are non-invasive, non-sterile, single-use products to be used independently or in combination with other incontinence products.
Classification:	Class I (according to Annex VIII of EU Regulation 2017/745 on medical devices) based on rule 1.
Conformity Assessment Route:	EU Regulation 2017/745 on medical devices Annex II, III, IV and V
GMDN Code:	61850
CND Code:	T040102
EMDN Code:	T04010201 Untackable underpad T04010202 Tackable underpad

We hereby declare, under our own sole responsibility, that the medical device(s) specified above meet the provisions of the European Council Regulation 2017/745 for medical devices, and any other relevant EU legislation applicable to the device(s). All supporting documentation is retained at the premises of the manufacturer.

This declaration is signed on behalf of the manufacturer, Ontex BV, and is issued at the address of the manufacturer.

Bart Waterschoot
PRRC

2022-08-08

Date (YYYY-MM-DD)

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Appendix
Models

Alvita Bed Pads

Catalog/Reference/Product Number or code	Product name and description	Classification, Rule
9959939	Alvita Bed Pad 60x90cm	I, 1