EU Declaration of Conformity – UNDERPAD

Manufacturer Name:	Ontex BV
Manufacturer Address:	Korte Keppestraat 21- B-9320 Aalst - Belgium
SRN (Single Registration Number):	BE-MF-000003544
Basic UDI-DI:	5414874UnderpadsUU
Product Name:	Underpads (see attached Appendix Models)
Product Code:	See attached Appendix Models
Intended Purpose:	The intended purpose of 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 disposable diapers 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 – Absorbent underpad, non-antimicrobial
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.



Chloé Vandevelde
PRRC

2026-09-29
Date (YYYY-MM-DD)

EU Declaration of Conformity

Appendix
Models

Lille Classic Bed		
Catalog/Reference/Product Number or code	**Product name and description**	**Classification, Rule**
LFBD8111	Classic Bed Extra 40X60	I, 1
LFBD8211	Classic Bed Extra 60X60	I, 1
LFBD8221	Classic Bed Super 60X60	I, 1
LFBD8311	Classic Bed Extra 60X75	I, 1
LFBD8401	Classic Bed Basic 60X90	I, 1
LFBD8411	Classic Bed Extra 60X90	I, 1
LFBD8411MM	Classic Bed Extra 60X90	I, 1
LFBD8415	Classic Bed Super 60X90	I, 1
LFBD8421	Classic Bed Maxi 60X90	I, 1
LFBD8511	Classic Bed Extra 90X180	I, 1
20914852	Vivactive Bed Plus 60x40cm x 15	I, 1