

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: 5414874HeavyIncoG5

Product Name: Incontinence products for Heavy Incontinence – see list attached

Product Code: See attached list

Intended Purpose: The intended purpose of the Heavy Inco product family is to collect urine and/or faeces. The devices are non-invasive, non-sterile, single-use disposable diapers to be used independently or in combination with a fixation pant.

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: 41588 – Adults Pants, Junior Pants
11239 – All-In-One Belt
35817 – Shaped Pads

CND Code: T040101

EMDN Code: T04010103 – Adult Pants, Junior Pants, All-In-One, Belt
T04010102 - Shaped Pads

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 All-In-One Pants

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
9959980	Alvita All in One Slip Super Medium	I, 1
9959997	Alvita All in One Slip Maxi Medium	I, 1
9960003	Alvita All in One Slip Super Large	I, 1
9960026	Alvita All in One Slip Maxi Large	I, 1
9960961	Alvita All in One Slip Maxi XL	I, 1

Alvita Absorbent Pants

Catalog/Reference/Product Number or code	Product name and description	Classification Rule
9959945	Alvita Pants Super Medium	I, 1
9959951	Alvita Pants Super Large	I, 1
9959968	Alvita Pants Maxi Large	I, 1
9959974	Alvita Pants Maxi Medium	I, 1
9959969	Alvita Pants Maxi XL	I, 1