

EU DECLARATION OF CONFORMITY

Company: Essity Hygiene and Health AB
SE-405 03 Göteborg
Sweden
Visitor's address: Mölndals Bro 2, Mölndal, Sweden

SRN number: SE-MF-000000004

Product assortment: TENA Comfort Ultima

Basic UDI-DI: 7322540100736V

Medical devices: See enclosed list

Risk class: Class I

Common Specification: N/A

Notified Body: N/A, Since class I device

Declaration: We hereby declare being the manufacturer* of the medical devices according to the enclosed article number list, and that the devices are in conformity with Medical Device Regulation (EU) 2017/745 (MDR) and fulfil all relevant safety and functional requirements in MDR.

The devices are classified in according to Annex VIII in MDR. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Intended use: The devices are intended for incontinence care

GMDN code: 11239

EMDN code: T04010102

Signatory: Mölndal, on 2022-04-26



Romana Stefek
Global Regulatory Affairs/Product Safety Director
PRRC, LM Essity Hygiene and Health AB

* per definition in Medical Device Regulation (EU) 2017/745

This declaration is valid until new version is issued.

Seat: Göteborgs kommun. Registration number: SE556007-2356

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Document Name	Document ID	Version
Declaration of Conformity	FORM-00733	6.0

Article Number	Article	UDI-DI
759205	Tena Comfort Ultima	7322540454826

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