

EU DECLARATION OF CONFORMITY

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

SRN number: SE-MF-000000004

hereby declares being the manufacturer* of the medical devices Incontinence Female Liners 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 requirements in MDR.

The devices are intended for incontinence care and are classified in Class I according to Annex VIII in MDR.

The GMDN code is 11239, the EMDN/CND code is T04010102 and the Basic UDI-DI is 7322540100926Z.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

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

Mölndal, on 2021-02-15



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

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	4.0

Article number	Article	UDI-DI number
100013	TENA Discreet Mini Magic 300x1 A	7322541238807
100014	TENA Discreet Ultra Mini 330x1 A	7322541239088
100015	TENA Discreet Ultra Mini Plus 260x1 A	7322541240107
100018	TENA Discreet Mini Magic 300x1 B	7322541241067
100019	TENA Discreet Ultra Mini 330x1 B	7322541241258
100021	TENA Discreet Ultra Mini Plus 260x1 B	7322541241494
100022	TENA Lady Slim Mini Magic 300x1 C	7322541241586
100023	TENA Lady Slim Ultra Mini 330x1 C	7322541241760
100024	TENA Lady Slim Ultra Mini Plus 260x1 C	7322541241890
100025	TENA Silh Noir Normal Liner 300x1 A	7322541241951
100026	TENA Silh Noir Normal Liner 300x1 B	7322541242118
100360	LbT Light Liner 300x1 AB	7322541271194
100361	LbT Liner 330x1 AB	7322541271279
100362	LbT Long liner 260x1 AB	7322541271330
100363	LbT Liner ew 276x1 AB	7322541271408
100364	LbT Long liner scented 260x1 AB	7322541271460
100515	TENA Lady Slim Ultra Mini 330x1 CD mix	7322541345949
210454	TENA lady Ultra Mini Plus	7322540226102
211002	TENA lady Ultra Mini	7322540019971
211174	lights by TENA Long Liner 4x20p B1	7322540557466
211398	lights by TENA Long Liner 4x20p B3	7322540588156
211406	TENA Discreet Ultra Mini Plus 4x24p B3/B5/B8 SRP code (TENA Lady Discreet UMP 4x24p B2 code)	7322540226058
211496	TENA Lady Slim Ultra Mini 6x14p SRP RU	7322541321677
211519	TENA Silh Noir Normal Liner 10x26 B1 SRP	7322541146829
757038	TENA lady Slim UM 21x14p B4	7322540013658
757048	TENA Discreet Ultra Mini 21x14p UK SRP	7322541079462
757051	TENA Lady Slim UM 21x14p B6 SRP	7322541115832
757052	TENA Lady Slim Ultra Mini 21x14p B7 SRP	7322540013658
757053	TENA Lady UM 10x14p RU	7322540013658
757054	TENA Lady Slim UM 10x14p B7 SRP	7322541321677
760106	lights by TENA Liner 10x22p ew B3	7322540588170
760113	lights by TENA UT Normal 12x16p B3	7322540758849
760114	lights by TENA UT Normal wing 12x14p B3	7322540758863
760118	lights by TENA UT Normal 6x16p	7322540808490
760121	lights by TENA UT Normal wing, 6x14p B2	7322540809015
760122	lights by TENA Liner ew 5x22pcs	7322540808667
760123	lights by TENA Liner ew 10x22p ew B2	7322540808704
761000	lights by TENA Light Liner 12x28p B3	7322540490220

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761001	TENA Discreet Mini Magic 6x34p B5/B8 SRP code (TENA Lady Discreet MM 6x34p B2/B3)	7322540118056
761008	lights by TENA Light Liner 5x28p B1	7322540490220
761024	Lights by TENA Light Liner 5x28p B2	7322540718607
761025	Lights by TENA Light Liner 5x28p B3	7322540490220
761052	TENA Lady Slim Mini Magic 6x34p B6 SRP	7322540894714
761053	lights by TENA Light Liner 5x28p,SRU eC	7322540897937
761054	TENA Lady Disc MiMg 6x34p DACH RT	7322540938845
761063	TENA Discreet Mini Magic 6x34p B1 SRP	7322541081816
761064	TENA Discreet Mini Magic 6x34p B2/B9 SRP	7322541079349
761086	TENA lights Light Liner 5x28p B2 SRP	7322541343259
761109	lights by TENA Liner6x24p B1	7322540490268
761115	lights by TENA Liner 6x24p B2	7322540721515
761116	lights by TENA Liner 6x24p B3	7322540721539
761125	TENA Discreet Ultra Mini 10x28p B1 SRP Neu	7322541079585
761129	TENA lights Liner 6x24p B2 SRP	7322541343341
761130	TENA Lady Slim UM 10x28p B4	7310791247649
761139	TENA Discreet Ultra Mini 10x28p B3 SRP (TENA Lady Discreet UM 10x28p FR)	7322540662696
761148	lights by TENA Liner 3x48p Duo B1	7322540600735
761173	TENA Discreet Ultra Mini 10x28p B1 SRP	7322541079585
761174	TENA Discreet Ultra Mini 10x28p B2/B9 SRP	7322541079677
761175	TENA Discreet Ultra Mini 10x28p B4/B5/B8 SRP code	7310791247649
761176	TENA Lady Slim UM 10x28p B6 SRP	7322541116082
761177	TENA Lady Slim Ultra Mini 10x28p B7 SRP	7322541116167
761182	TENA Lady Slim 3x48p UM B6/ B7 SRP	7322541360577
761270	TENA Silh Noir Normal Liner 10x26 B1 SRP	7322541146737
761271	TENA Silh Noir N Liner 10x26p B2 PZN SRP	7322541146775
761272	TENA Silh Noir N Liner 10x26p B3/B8 SRP	7322541146829
761273	TENA Silh Noir Normal Liner 8x26p B1 SRP	7322541146737
761274	TENA Silh Noir N Liner 10x26 B4B5 SRP co	7322541157641
761803	lights by TENA Long Liner 6x20p bulk B1	7322540557466
761807	lights by TENA Long Liner 6x20p B3	7322540588156
761816	lights by TENA Long Liner 6x20p B2	7322540719642
761818	lights by TENA Long Liner 3x40p Duo B1	7322540785999
761822	lights by TENA Long Liner 6x20p, SRU eC	7322540894059
761824	TENA Lady Discr Ult MiPl 6x24p DACH RT	7322540938388
761825	lights by TENA Long Liner 12x20p B3	7322540588156
761826	lights by TENA Long Liner 3x40p Jumbo B3	7322540945942
761828	TENA Discreet Ultra Mini Plus 6x24p B1 SRP	7322541079899
761829	TENA Discreet Ultra Mini Plus 6x24p B2 SRP	7322541079967

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761830	TENA Discreet Ultra Mini Plus 12x24p B3/B5/B8 SRP code	7322540226058
761832	TENA Discreet Ultra Mini Plus 6x24p B3/B5/B8 SRP code	7322540226058
761833	TENA Discreet Ultra Mini Plus 6x24p B1 SRP Neu	7322541079899
761834	TENA Lady Slim UMP 6x24p B6 SRP	7322541116433
761838	TENA lights Long Liner 6x20p B2 SRP	7322541343686
761839	TENA lights Long Liner 3x40p CONV B4 SRP	7322541345840
761860	lights by TENA Long Liner Scented 6x18p B1	7322540946260
761861	lights by TENA Long Liner Scented 6x18p B2	7322540946307
761862	lights by TENA Long Liner Scented 6x18p B3	7322540946345

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EU PROHLÁŠENÍ O SHODĚ

Společnost

Essity Hygiene and Health AB

SE-405 03 Göteborg

Švédsko

Adresa pro návštěvy: Mölndals Bro 2, Mölndal

Číslo SRN: SE-MF-000000004

tímto prohlašuje, že je výrobcem* zdravotnických prostředků Incontinence Female Liners Inkontinenční vložky pro ženy dle příloženého seznamu a že tyto prostředky jsou v souladu s nařízením EU č. 2017/745 o zdravotnických prostředcích („nařízení“) a splňují všechny jeho příslušné požadavky.

Prostředky jsou určeny k péči o inkontinentní osoby a jsou klasifikovány jako třída I podle přílohy VIII nařízení.

GMDN kód je 11239, EMDN/CND kód je T04010102 a základní UDI-DI je 7322540100926Z.

Toto prohlášení o shodě se vydává na výhradní odpovědnost výrobce.

**podle definice v nařízení (EU) č. 2017/745 o zdravotnických prostředcích*

Mölndal, 15. února 2021

[podpis]

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Romana Stefek

Ředitelka pro globální regulatorní problematiku a bezpečnost výrobků
LM Essity Hygiene and Health AB

Toto prohlášení zůstává v platnosti do vydání nové verze.

Essity Hygiene and Health AB
SE-405 03 GÖTEBORG
Švédsko

Sídlo: Göteborgs kommun. Reg. číslo: SE556007-2356

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Název dokumentu	ID dokumentu	Verze
Prohlášení o shodě	FORMULÁŘ 00733	4.0

Číslo položky	Položka	Číslo UDI-DI
100013	TENA Discreet Mini Magic 300x1 A	7322541238807
100014	TENA Discreet Ultra Mini 330x1 A	7322541239088
100015	TENA Discreet Ultra Mini Plus 260x1 A	7322541240107
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761000	lights by TENA Light Liner 12x28p B3	7322540490220
761001	TENA Discreet Mini Magic 6x34p B5/B8 SRP code (TENA Lady Discreet MM 6x34p B2/B3)	7322540118056

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761830	TENA Discreet Ultra Mini Plus 12x24p B3/B5/B8 SRP code	7322540226058
761832	TENA Discreet Ultra Mini Plus 6x24p B3/B5/B8 SRP code	7322540226058
761833	TENA Discreet Ultra Mini Plus 6x24p B1 SRP Neu	7322541079899

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