

# 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:** Incontinence Female Liners

**Basic UDI-DI:** 7322540100926Z

**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 2022-06-10



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

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

This declaration is valid until new version is issued.

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Seat: Göteborgs kommun. Registration number: SE556007-2356

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

Article No.	Article Name	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
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	TENA Lights Liner Light 300x1 AB	7322541271194
100361	TENA Lights Liner Normal 330x1 AB	7322541271279
100362	TENA Lights Liner Long 260x1 AB	7322541271330
100363	TENA Lights Liner Normal EW 276x1 AB	7322541271408
100364	LbT Long liner scented 260x1 AB	7322541271460
100515	TENA Lady Slim Ultra Mini 330x1 CD mix	7322541345949
100594	TENA Dailies Long 300x1 DACH	7322541500683
211002	TENA lady Ultra Mini	7322540019971
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	TENA lights Liner 10x22p ew B3 SRP	7322540588170
760113	lights by TENA UT Normal 12x16p B3	7322540758849
760114	lights by TENA UT Normal wing 12x14p B3	7322540758863
760122	TENA lights Liner Normal 5x22p EW B1 SRP	7322540808667
760123	TENA lights Liner Norm 10x22p EWB3B4 SRP	7322540808704
761000	TENA lights Liner Discr 12x28p B3/B8 FSC	7322540490220
761001	TENA Discreet Mini Magic 6x34p B5/B8 SRP code (TENA Lady Discreet MM 6x34p B2/B3)	7322540118056
761008	TENA lights Liner Light 5x28p B1 SRP	7322540490220
761024	TENA lights Liner Discr 5x28p B4/B5 SRP	7322540718607
761025	TENA lights Liner Discr 5x28p B3/B8 FSC	7322540490220
761052	TENA Lady Slim Mini Magic 6x34p B6 SRP	7322540894714
761053	TENA lights Liner Light 5x28p SRU eC	7322540897937
761063	TENA Discreet Mini Magic 6x34p B1 SRP	7322541081816
761064	TENA Discreet Mini Magic 6x34p B2/B9 SRP	7322541079349
761086	TENA lights Liner Discr 5x28p B2 SRP	7322541343259
761109	TENA lights Liner Normal 6x24p B1 SRP	7322540490268

Document Name	Document ID	Version
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761115	TENA lights Liner Normal 6x24p B4/B5 SRP	7322540721515
761116	TENA lights Liner Normal 6x24p B3/B8 FSC	7322540721539
761125	TENA Discreet Ultra Mini 10x28p B1 SRP Neu	7322541079585
761129	TENA lights Liner Normal 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	TENA lights Liner Norm 3x48p Duo B1 SRP	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
761183	TENA Lady Slim UM 3x48p B6/B7 SRP+sticker	7322541403359
761201	TENA Dailies Normal 10x24p B2 SRP	7322541434223
761202	TENA Dailies Long 10x22p B2 SRP	7322541434308
761203	TENA Dailies Extra Long 10x20p B2 SRP	7322541434414
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
761290	TENA Lady Slim Micro 12x18p B6/B7 SRP	7322541360966
761803	TENA lights Liner Long 6x20p bulk B1 SRP	7322540557466
761807	TENA lights Liner Long 6x20p B3/B8 FSC	7322540588156
761816	TENA lights Liner Long 6x20p B4/B5 SRP	7322540719642
761818	TENA lights Liner Long 3x40p Duo B1 SRP	7322540785999
761822	TENA lights Liner Long 6x20p SRU eC	7322540894059
761824	TENA Lady Discr Ult MiPI 6x24p DACH RT	7322540938388
761825	TENA lights Liner Long 12x20p B3/B8 FSC	7322540588156
761826	TENA lights Long Liner 3x40p JumboB3 SRP	7322540945942
761828	TENA Discreet Ultra Mini Plus 6x24p B1 SRP	7322541079899
761829	TENA Discreet Ultra Mini Plus 6x24p B2 SRP	7322541079967
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 Liner Long 6x20p B2 SRP	7322541343686
761839	TENA lights Liner Long 3x40p CONV IT SRP	7322541345840
761861	lights by TENA Long Liner Scented 6x18p B2	7322540946307
761862	lights by TENA Long Liner Scented 6x18p B3	7322540946345

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## PROHLÁŠENÍ O SHODĚ ES

**Společnost:** Essity Hygiene and Health AB  
SE-405 03 Göteborg  
Sweden  
Adresa: Mölndals Bro 2, Mölndal, Sweden  
  
SRN number: SE-MF-000000004

**Produkty:** Incontinence Female Liners

**Basic UDI-DI:** 7322540100926Z

**Zdravotnický prostředek:** Seznam níže  
**Riziková třída:** Třída I

**Specifikace:** N/A

**Notifikovaná osoba:** N/A, riziková třída I

**Prohlášení:** tímto prohlašujeme jako výrobce\* zdravotnických prostředků uvedených v seznamu níže, že zdravotnické prostředky splňují příslušná ustanovení Nařízení o zdravotnických prostředcích (EU) 2017/745 (MDR) a splňují veškeré relevantní požadavky na bezpečnost a funkčnost stanovené MDR. Prostředky jsou klasifikované dle přílohy VIII MDR. Toto prohlášení o shodě je vydáno dle výhradní zodpovědnosti výrobce.

**Účel použití:** Prostředky jsou určeny pro inkontinenční péči.  
**GMDN kód:** 11239  
**EMDN kód:** T04010102

### Signatory:

Mölndal, dne 10.6.2022

Romana Stefek

Global Regulatory Affairs/Product Safety Director

PRRC, LM Essity Hygiene and Health AB

\* dle definice v nařízení o zdravotnických prostředcích (EU) 2017/745

Toto prohlášení zůstává v platnosti, dokud není nahrazeno novou verzí.

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[www.essity.com](http://www.essity.com)

Číslo položek	Položka	UDI-DI číslo
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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