

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 Laminate Pants

Basic UDI-DI: 73225401008676

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: 41588

EMDN code: T04010103

Signatory: Mölndal, on Apr 24, 2024



Romana Stefek
Global Regulatory Affairs Director
PRRC Medical Devices, Cosmetics/Biocides, Certified Products

* 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

Essity Hygiene and Health AB
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www.essity.com

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

Article number	Article Name	UDI-DI
54341	TENA Lady Pants Disc Plus M 4x18 MEA	768702543415
54342	TENA Lady Pants Disc Plus L 4x16 MEA	768702543422
54950	TENA Pants Discreet Plus XL 4x14 MEA	380040549500
100034	TENA Silh. Normal M 72x1 Whi.pri LW, A	7322541242996
100035	TENA Silh. Normal M 72x1 Whi.pri LW, B	7322541243108
100036	TENA Silh. Normal M 72x1 Whi.pri LW, C	7322541243511
100037	TENA Silh. Normal L 72x1 Whi.pri LW, A	7322541243672
100038	TENA Silh. Normal L 72x1 Whi.pri LW, B	7322541243795
100039	TENA Silh. Normal M 72x1, Black LW, A	7322541243887
100041	TENA Silh. Normal M 72x1, Black LW, B	7322541243979
100042	TENA Silh. Normal L 72x1 Whi.pri LW, C	7322541244198
100043	TENA Silh. Normal L 72x1, Black LW, A	7322541244297
100044	TENA Silh. Normal L 72x1, Black LW, B	7322541244396
100176	TENA Men PU Maxi S/M, 56x1, A	7322541248646
100177	TENA Men PU Maxi S/M, 56x1, B	7322541248752
100178	TENA Men PU Maxi S/M, 56x1, C	7322541248868
100179	TENA Men PU Maxi L/XL, 56x1, A	7322541248981
100180	TENA Men PU Maxi L/XL, 56x1, B	7322541249100
100181	TENA Men PU Maxi L/XL, 56x1, C	7322541249322
100475	TENA Lady Pant Disc Plus XL 40x1, MEA, D	7322541319445
100540	TENA Lady Pant Disc Plus M 63x1, MEA, D	7322541380056
100541	TENA Lady Pant Disc Plus L 63x1, MEA, D	7322541380247
100593	TENA Lady Pant Disc Plus L 56x1, MEA, D	7322541456546
100597	TENA Lady Pant Disc Plus M 56x1, MEA, D	7322541705309
100628	TENA Silh. Normal M 72x1, Black LW, C	7322541770055
100629	TENA Silh. Normal L 72x1, Black LW, C	7322541770062
780100	TENA Silhouette Plus M 6x12p LW White Printed FSC	7322542075043
780101	TENA Silhouette Plus M 2x12p LW White Printed SRP FSC	7322542075043
780102	TENA Silhouette Plus M 2x12p LW White Printed SRP DE NL FSC	7322542075104
780103	TENA Silhouette Plus M 6x12p LW Blanc FR NL FSC	7322542075135
780105	TENA Silhouette Plus M 6x12p LW Blanc CODE FSC	7322542075197
780109	TENA Silhouette Plus M 6x12p LW Blanc FR DP FSC	7322542148006
780111	TENA Silhouette Plus M 3x12p LW White Printed eC NEU FSC	7322542147153
780120	TENA Silhouette Plus L 6x10p LW White Printed FSC	7322542075975
780121	TENA Silhouette Plus L 2x10p LW White Printed SRP FSC	7322542075975
780122	TENA Silhouette Plus L 2x10p LW White Printed SRP DE NL FSC	7322542076330
780123	TENA Silhouette Plus L 6x10p LW Blanc FR NL FSC	7322542076514
780125	TENA Silhouette Plus L 6x10p LW Blanc CODE FSC	7322542076873
780129	TENA Silhouette Plus L 6x10p LW Blanc FR DP FSC	7322542148228
780131	TENA SilhouettePlus L 3x10p LW White Printed eC NEU FSC	7322542147177

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780201	TENA Silhouette Plus M 2x12p LW Black SRP FSC	7322542086803
780202	TENA Silhouette Plus M 2x12p LW Black SRP DE NL FSC	7322542146989
780203	TENA Silhouette Plus M 6x12p LW Noir FR NL FSC	7322542087183
780205	TENA Silhouette Plus M 2x12p LW Noir SRP CODE FSC	7322542087428
780206	TENA Discreet LW M 2x12p SRP Black AUS FSC	7322542104156
780207	TENA Silhouette Plus M 6x12p LW Noir FR DP FSC	7322542146811
780221	TENA Silhouette Plus L 2x10p LW Black SRP FSC	7322542087893
780222	TENA Silhouette Plus L 2x10p LW Black SRP DE NL FSC	7322542088012
780223	TENA Silhouette Plus L 6x10p LW Noir FR NL FSC	7322542088135
780225	TENA Silhouette Plus L 2x10p LW Noir SRP CODE FSC	7322542088258
780226	TENA Discreet LW L 2x10p SRP Black AUS FSC	7322542104255
780227	TENA Silhouette Plus L 6x10p LW Noir FR DP FSC	7322542148167
780300	TENA Silhouette Plus M 6x9p HW Cream FSC	7322542088487
780301	TENA Silhouette Plus M 2x9p HW Cream SRP FSC	7322542088487
780302	TENA Silhouette Plus M 2x9p HW Crème SRP DE NL FSC	7322542088708
780303	TENA Silhouette Plus M 6x9p HW Crème FR NL FSC	7322542088814
780304	TENA Silhouette Plus M 6x9p HW Crème CODE FSC	7322542088920
780320	TENA Silhouette Plus L 6x8p HW Cream FSC	7322542090213
780321	TENA Silhouette Plus L 2x8p HW Cream SRP FSC	7322542090213
780322	TENA Silhouette Plus L 2x8p HW CrèmeSRP DE NL FSC	7322542090473
780323	TENA Silhouette Plus L 6x8p HW Crème FR NL FSC	7322542090602
780324	TENA Silhouette Plus L 6x8p HW Crème CODE FSC	7322542090732
780400	TENA Silhouette Plus M 2x9p HW Black SRP FSC	7322542091227
780401	TENA Silhouette Plus M 6x9p HW Noir FR NL CODE FSC	7322542091333
780420	TENA Silhouette Plus L 2x8p HW Black SRP FSC	7322542092118
780421	TENA Silhouette Plus L 6x8p HW Noir FR NL CODE FSC	7322542155806
795506	TENA Silhouette Normal Low Waist Blanc M, 6x6 SRP	7322540679137
795509	TENA Silhouette Normal Low Waist Blanc M 6x6 eC	7322540897081
795510	TENA Silhouette Normal Low Waist Noir M, 3x10 SRP	7322541056494
795511	TENA Silhouette Normal Low Waist Noir M, 6x10, FR	7322541056531
795512	TENA Silhouette Normal Low Waist Blanc M, 6x12	7322540488258
795514	TENA Silhouette Normal Low Waist Blanc M, 6x12, NEU	7322540488258
795515	TENA Silhouette Normal Low Waist Noir M, 3x10, CODE	7322541056579
795516	TENA Silhouette Normal Low Waist Noir M, 6x10	7322541056494
795520	TENA Discr Norm M 3x10 SRP Black LW, AUS	7322541216508
795521	TENA Silh. Norm M 6x6 Whi.pr LW,RTeC,NEU	7322541313603
795522	TENA Silhouette Normal Low Waist Blanc M, 6x12, CODE, IT	7322540488258
795525	TENA Silh. Normal M, 6x6 SRP, Black LW	7322541431215
795527	TENA Silh. Normal M 6x10p Black LW FR DP	7322542132623
795532	TENA Silhouette Normal Low Waist Blanc M, 6x12, FR	7322540532852
795536	TENA Silh. Normal M 6x12p WhiPr LW FR DP	7322542132777
795605	TENA Silhouette Normal Low Waist Blanc L, 6x5 SRP	7322540679212

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Declaration of Conformity	FORM-00733	6.0

795608	TENA Silhouette Normal Low Waist Blanc L 6x5 eC	7322540897074
795610	TENA Silhouette Normal Low Waist Blanc L, 6x10	7322540488555
795614	TENA Silhouette Normal Low Waist Blanc L, 6x10, NEU	7322540488555
795616	TENA Silhouette Normal Low Waist Noir L, 3x9 SRP	7322541056708
795617	TENA Silhouette Normal Low Waist Noir L, 6x9, FR	7322541056746
795619	TENA Silhouette Normal Low Waist Noir L, 3x9, CODE	7322541056784
795620	TENA Silhouette Normal Low Waist Blanc L, 6x10, CODE, IT	7322540488555
795621	TENA Silhouette Normal Low Waist Noir L, 6x9	7322541056708
795623	TENA Discr Norm L 3x9 SRP Black LW, AUS	7322541216607
795626	TENA Silh. Norm L 6x5 Whi.pr LW,RTeC,NEU	7322541313795
795627	TENA Silh. Normal L, 6x5 SRP, Black LW	7322541431352
795630	TENA Silhouette Normal Low Waist Blanc L, 6x10, FR	7322540532876
795638	TENA Silh. Normal L 6x9p Black LW FR DP	7322542132913
795639	TENA Silh. Normal L 6x10p WhiPr LW FR DP	7322542133071
795732	TENA Pants Discreet M 6x12p NEU NSW	7322542315767
795733	TENA Pants Discreet L 6x10p NEU NSW	7322542315927
796010	TENA Silhouette Normal Low Waist Blanc L, 3x10 SRP	7322540819304
796012	TENA Silhouette Normal Low Waist Blanc M, 3x12 SRP	7322540819281
797508	TENA Lady Silhouette Nuit Medium	7322540679151
797512	TENA Silhouette Discreet Plus High Waist Blanc M, 6x12	7322540483529
797513	TENA Silh Lady Pant Disc Plus M 6x12 MEA	7322540993219
797518	TENA Silhouette Night High Waist Blanc M, 6x8	7322540822120
797519	TENA Lady Pants Night M, 6x8p, South	7322540968163
797605	TENA Lady Pants Night Large, SRP	7322540679250
797607	TENA Lady Silhouette Nuit Large	7322540679236
797610	TENA Silhouette Discreet Plus High Waist Blanc L, 6x10	7322540483567
797613	TENA Silh Lady Pant Disc Plus L 6x10 MEA	7322540993318
797617	TENA Silhouette Night High Waist Blanc L, 6x7	7322540822144
797618	TENA Lady Pants Night L, 6x7pcs, South	7322540968255
798300	TENA Men Protective Underwear L4 M/L	7322540483970
798306	TENA Men PU Maxi L/XL 4x10p, INT	7322540886238
798307	TENA Men PU Maxi L/XL 3x8p, INT (SRP)	7322540886252
798308	TENA Men PU Maxi S/M 4x12p, INT	7322540886276
798309	TENA Men PU Maxi S/M 3x10p, INT (SRP)	7322540886290
798310	TENA Men PU Maxi L/XL 4x10p, Neutral	7322540886238
798311	TENA Men PU L4 L 4x10, IT Sticker	7322540886238
798312	TENA Men PU Maxi S/M 4x12p, Neutral	7322540886276
798313	TENA Men PU L4 M 4x12, IT Sticker	7322540886276
798314	TENA Men PU Maxi L/XL 4x10p, eC	7322540897098
798315	TENA Men PU Maxi S/M 4x12p, eC	7322540897104
798316	TENA Men PU Maxi L/XL 4x10p, MEA	7322540936254
798319	TENA Men PU Maxi S/M 4x10p, IT	7322541201078

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

798321	TENA Men PU Maxi L/XL 4x8p, IT	7322541201139
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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: TENA Laminate Pants

Basic UDI-DI: 73225401008676

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: 41588
EMDN kód: T04010103

Signatory:

Mölndal, dne 24.4.2024
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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Sídlo: Göteborgs kommun. Číslo registrace: SE556007-2356

Číslo položek	Položka	UDI-DI číslo
Article number	Article Name	UDI-DI
54341	TENA Lady Pants Disc Plus M 4x18 MEA	768702543415
54342	TENA Lady Pants Disc Plus L 4x16 MEA	768702543422
54950	TENA Pants Discreet Plus XL 4x14 MEA	380040549500
100034	TENA Silh. Normal M 72x1 Whi.pri LW, A	7322541242996
100035	TENA Silh. Normal M 72x1 Whi.pri LW, B	7322541243108
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100044	TENA Silh. Normal L 72x1, Black LW, B	7322541244396
100176	TENA Men PU Maxi S/M, 56x1, A	7322541248646
100177	TENA Men PU Maxi S/M, 56x1, B	7322541248752
100178	TENA Men PU Maxi S/M, 56x1, C	7322541248868
100179	TENA Men PU Maxi L/XL, 56x1, A	7322541248981
100180	TENA Men PU Maxi L/XL, 56x1, B	7322541249100
100181	TENA Men PU Maxi L/XL, 56x1, C	7322541249322
100475	TENA Lady Pant Disc Plus XL 40x1, MEA, D	7322541319445
100540	TENA Lady Pant Disc Plus M 63x1, MEA, D	7322541380056
100541	TENA Lady Pant Disc Plus L 63x1, MEA, D	7322541380247
100593	TENA Lady Pant Disc Plus L 56x1, MEA, D	7322541456546
100597	TENA Lady Pant Disc Plus M 56x1, MEA, D	7322541705309
100628	TENA Silh. Normal M 72x1, Black LW, C	7322541770055
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780100	TENA Silhouette Plus M 6x12p LW White Printed FSC	7322542075043
780101	TENA Silhouette Plus M 2x12p LW White Printed SRP FSC	7322542075043
780102	TENA Silhouette Plus M 2x12p LW White Printed SRP DE NL FSC	7322542075104
780103	TENA Silhouette Plus M 6x12p LW Blanc FR NL FSC	7322542075135
780105	TENA Silhouette Plus M 6x12p LW Blanc CODE FSC	7322542075197
780109	TENA Silhouette Plus M 6x12p LW Blanc FR DP FSC	7322542148006
780111	TENA Silhouette Plus M 3x12p LW White Printed eC NEU FSC	7322542147153
780120	TENA Silhouette Plus L 6x10p LW White Printed FSC	7322542075975
780121	TENA Silhouette Plus L 2x10p LW White Printed SRP FSC	7322542075975
780122	TENA Silhouette Plus L 2x10p LW White Printed SRP DE NL FSC	7322542076330
780123	TENA Silhouette Plus L 6x10p LW Blanc FR NL FSC	7322542076514
780125	TENA Silhouette Plus L 6x10p LW Blanc CODE FSC	7322542076873
780129	TENA Silhouette Plus L 6x10p LW Blanc FR DP FSC	7322542148228
780131	TENA SilhouettePlus L 3x10p LW White Printed eC NEU FSC	7322542147177

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Sídlo: Göteborgs kommun. Číslo registrace: SE556007-2356

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780202	TENA Silhouette Plus M 2x12p LW Black SRP DE NL FSC	7322542146989
780203	TENA Silhouette Plus M 6x12p LW Noir FR NL FSC	7322542087183
780205	TENA Silhouette Plus M 2x12p LW Noir SRP CODE FSC	7322542087428
780206	TENA Discreet LW M 2x12p SRP Black AUS FSC	7322542104156
780207	TENA Silhouette Plus M 6x12p LW Noir FR DP FSC	7322542146811
780221	TENA Silhouette Plus L 2x10p LW Black SRP FSC	7322542087893
780222	TENA Silhouette Plus L 2x10p LW Black SRP DE NL FSC	7322542088012
780223	TENA Silhouette Plus L 6x10p LW Noir FR NL FSC	7322542088135
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780303	TENA Silhouette Plus M 6x9p HW Crème FR NL FSC	7322542088814
780304	TENA Silhouette Plus M 6x9p HW Crème CODE FSC	7322542088920
780320	TENA Silhouette Plus L 6x8p HW Cream FSC	7322542090213
780321	TENA Silhouette Plus L 2x8p HW Cream SRP FSC	7322542090213
780322	TENA Silhouette Plus L 2x8p HW CrèmeSRP DE NL FSC	7322542090473
780323	TENA Silhouette Plus L 6x8p HW Crème FR NL FSC	7322542090602
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780400	TENA Silhouette Plus M 2x9p HW Black SRP FSC	7322542091227
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780420	TENA Silhouette Plus L 2x8p HW Black SRP FSC	7322542092118
780421	TENA Silhouette Plus L 6x8p HW Noir FR NL CODE FSC	7322542155806
795506	TENA Silhouette Normal Low Waist Blanc M, 6x6 SRP	7322540679137
795509	TENA Silhouette Normal Low Waist Blanc M 6x6 eC	7322540897081
795510	TENA Silhouette Normal Low Waist Noir M, 3x10 SRP	7322541056494
795511	TENA Silhouette Normal Low Waist Noir M, 6x10, FR	7322541056531
795512	TENA Silhouette Normal Low Waist Blanc M, 6x12	7322540488258
795514	TENA Silhouette Normal Low Waist Blanc M, 6x12, NEU	7322540488258
795515	TENA Silhouette Normal Low Waist Noir M, 3x10, CODE	7322541056579
795516	TENA Silhouette Normal Low Waist Noir M, 6x10	7322541056494
795520	TENA Discr Norm M 3x10 SRP Black LW, AUS	7322541216508
795521	TENA Silh. Norm M 6x6 Whi.pr LW,RTeC,NEU	7322541313603
795522	TENA Silhouette Normal Low Waist Blanc M, 6x12, CODE, IT	7322540488258
795525	TENA Silh. Normal M, 6x6 SRP, Black LW	7322541431215
795527	TENA Silh. Normal M 6x10p Black LW FR DP	7322542132623
795532	TENA Silhouette Normal Low Waist Blanc M, 6x12, FR	7322540532852
795536	TENA Silh. Normal M 6x12p WhiPr LW FR DP	7322542132777
795605	TENA Silhouette Normal Low Waist Blanc L, 6x5 SRP	7322540679212

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795608	TENA Silhouette Normal Low Waist Blanc L 6x5 eC	7322540897074
795610	TENA Silhouette Normal Low Waist Blanc L, 6x10	7322540488555
795614	TENA Silhouette Normal Low Waist Blanc L, 6x10, NEU	7322540488555
795616	TENA Silhouette Normal Low Waist Noir L, 3x9 SRP	7322541056708
795617	TENA Silhouette Normal Low Waist Noir L, 6x9, FR	7322541056746
795619	TENA Silhouette Normal Low Waist Noir L, 3x9, CODE	7322541056784
795620	TENA Silhouette Normal Low Waist Blanc L, 6x10, CODE, IT	7322540488555
795621	TENA Silhouette Normal Low Waist Noir L, 6x9	7322541056708
795623	TENA Discr Norm L 3x9 SRP Black LW, AUS	7322541216607
795626	TENA Silh. Norm L 6x5 Whi.pr LW,RTeC,NEU	7322541313795
795627	TENA Silh. Normal L, 6x5 SRP, Black LW	7322541431352
795630	TENA Silhouette Normal Low Waist Blanc L, 6x10, FR	7322540532876
795638	TENA Silh. Normal L 6x9p Black LW FR DP	7322542132913
795639	TENA Silh. Normal L 6x10p WhiPr LW FR DP	7322542133071
795732	TENA Pants Discreet M 6x12p NEU NSW	7322542315767
795733	TENA Pants Discreet L 6x10p NEU NSW	7322542315927
796010	TENA Silhouette Normal Low Waist Blanc L, 3x10 SRP	7322540819304
796012	TENA Silhouette Normal Low Waist Blanc M, 3x12 SRP	7322540819281
797508	TENA Lady Silhouette Nuit Medium	7322540679151
797512	TENA Silhouette Discreet Plus High Waist Blanc M, 6x12	7322540483529
797513	TENA Silh Lady Pant Disc Plus M 6x12 MEA	7322540993219
797518	TENA Silhouette Night High Waist Blanc M, 6x8	7322540822120
797519	TENA Lady Pants Night M, 6x8p, South	7322540968163
797605	TENA Lady Pants Night Large, SRP	7322540679250
797607	TENA Lady Silhouette Nuit Large	7322540679236
797610	TENA Silhouette Discreet Plus High Waist Blanc L, 6x10	7322540483567
797613	TENA Silh Lady Pant Disc Plus L 6x10 MEA	7322540993318
797617	TENA Silhouette Night High Waist Blanc L, 6x7	7322540822144
797618	TENA Lady Pants Night L, 6x7pcs, South	7322540968255
798300	TENA Men Protective Underwear L4 M/L	7322540483970
798306	TENA Men PU Maxi L/XL 4x10p, INT	7322540886238
798307	TENA Men PU Maxi L/XL 3x8p, INT (SRP)	7322540886252
798308	TENA Men PU Maxi S/M 4x12p, INT	7322540886276
798309	TENA Men PU Maxi S/M 3x10p, INT (SRP)	7322540886290
798310	TENA Men PU Maxi L/XL 4x10p, Neutral	7322540886238
798311	TENA Men PU L4 L 4x10, IT Sticker	7322540886238
798312	TENA Men PU Maxi S/M 4x12p, Neutral	7322540886276
798313	TENA Men PU L4 M 4x12, IT Sticker	7322540886276
798314	TENA Men PU Maxi L/XL 4x10p, eC	7322540897098
798315	TENA Men PU Maxi S/M 4x12p, eC	7322540897104
798316	TENA Men PU Maxi L/XL 4x10p, MEA	7322540936254
798319	TENA Men PU Maxi S/M 4x10p, IT	7322541201078
798321	TENA Men PU Maxi L/XL 4x8p, IT	7322541201139

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