



Management System Certificate

Certificate No.:
216366-2017-AQ-SWE-NA-PS Rev. 2.0

Project No.:
PRJC-361692-2012-MS-C-SWE

Initial Certification Date:
08 JULY 2009

Valid Until:
08 JULY 2021

This is to certify that the management system of:

Essity Hygiene and Health AB

Mölndals bro 2, 431 31 MÖLNDAL, Sweden

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Development of medical devices for incontinence care.

Place and Date:
Høvik, 25 June 2018



For:
DNV GL PRESAFE AS

Eugenie Winger Husebye

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC DECLARATION OF CONFORMITY

Essity Hygiene and Health AB

SE-405 03 Göteborg

Sweden

hereby declares that the medical devices TENA Pants Unisex for incontinence care according to the enclosed article list, fulfill the provisions of Council Directive 93/42/EEC of 14 June 1993, amended as relevant.

The products are classified as medical devices class I according to said Directive and the GMDN code is 41588.

The conformity assessment is carried out in accordance with Annex VII of the Medical Device Directive 93/42/EC.

The products are hereby also in conformity with all relevant parts of Swedish legislation regarding requirements of the Medical Devices Directive and corresponding regulation from Medical Products Agency. The articles are notified with Swedish competent authority, Medical Products Agency.

Mölnadal, on May 8th 2020



Essity Hygiene and Health AB
405 03 GÖTEBORG
SWEDEN

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

This Declaration of Conformity is valid until replaced with a new version and no longer than May 25th, 2021. It is managed by SCR GBIS Certified Products Department - Hygiene

Seat: Göteborgs kommun. Registration number: SE556007-2356

Essity Hygiene and Health AB
SE-405 03 GÖTEBORG
Sweden

Visitors' address:
Mölnåls Bro 2, Mölnåls
Phone: +46 31 746 00 00
www.essity.com

TENA Pants Unisex Assortment

Article number	Article
100148	TENA Pants Normal L, 56x1, WI, Ps B
100149	TENA Pants Normal M, 56x1, WI, Ps B
100150	TENA Pants Normal M, 56x1, Ps AB
100151	TENA Pants Normal M, 56x1, Ps C
100153	TENA Pants Normal M, 56x1, C
100155	TENA Pants Original Normal M, 56x1, A
100156	TENA Pants Normal L, 56x1, Ps AB
100157	TENA Pants Normal L, 56x1, Ps C
100158	TENA Pants Normal L, 56x1, C
100159	TENA Pants Original Normal L, 56x1 A
100160	TENA Pants Night Super M, 42x1, WI, Ps, B
100161	TENA Pants Night Super M, 42x1, Ps, AB
100162	TENA Pants Night Super M, 42x1, Ps, C
100163	TENA Pants Night Super L, 42x1, WI, Ps, B
100164	TENA Pants Night Super L, 42x1, Ps, AB
100165	TENA Pants Night Super L, 42x1, Ps, C
211257	TENA Pants Super Medium, 2x12, SRP
211259	TENA Pants Plus L, 2x8
211264	TENA Pants Plus M, 2x9
211266	TENA Pants Super L, 2x12
782518	TENA Pants Plus Classic M, 4x14p, NEU
782531	TENA Pants Plus Classic M, 8x14p NEU, NSW
782618	TENA Pants Plus Classic L, 8x10pcs NEU, NSW
791415	TENA Pants NORMAL, Small, int
791465	TENA Pants NORMAL, Small, neutr.
791470	ORLYS Pants Día P, 4x10
791510	TENA Pants Normal Medium, 4x10, east
791511	TENA Pants Normal Medium, 4x10p, East
791520	TENA Pants Normal M, 4x10, RU
791528	TENA Pants Normal Medium, 4x18, int
791530	TENA Pants Normal Medium, 2x30, east
791531	TENA Pants Normal Medium, 2x30p, East
791540	TENA Pants Normal M, 4x10, Rt
791548	TENA Pants Original Normal Medium, 4x18, DE
791568	TENA Pants Normal Medium, 4x18, neutr.
791570	ORLYS Pants Día M, 2x30
791571	ORLYS Pants Día M, 8x10, ES
791580	TENA Pants Normal M, 4x10p, MEIA
791610	TENA Pants Normal Large, 4x10, east
791611	TENA Pants Normal Large, 4x10p, East
791620	TENA Pants Normal L, 4x10, RU
791628	TENA Pants Normal Large, 4x18, int
791630	TENA Pants Normal Large, 2x30, east
791631	TENA Pants Normal Large, 2x30p, East
791640	TENA Pants Normal L, 4x10, Rt
791648	TENA Pants Original Normal Large, 4x18, DE
791668	TENA Pants Normal Large, 4x18, neutr.
791670	ORLYS Pants Día G, 8x10

791680	TENA Pants Normal M, 4x10, MEIA
791715	TENA Pants NORMAL XL, int.
791716	TENA Pants Normal XL, 6x15, Int., Ps
791717	TENA Pants Normal XL, 6x15, NEU, NSW,Ps
791765	TENA Pants Normal XL, neutr.
792100	TENA Pants Discreet M
792108	TENA Pants Discreet M
792214	TENA Pants Plus XXS, 14pcs
792300	TENA Pants Discreet, M
792314	TENA Pants PLUS XS, 4x14
792315	TENA Pants Plus Basic XS, 4x14, Neu
792316	TENA Pants Plus Basic S, 4x14, Neu
792317	TENA Pants Super Basic S, 4x12, Neu
792318	TENA Pants Plus Basic M, 4x14, Neu
792319	TENA Pants Super Basic M, 4x12, Neu
792320	TENA Pants Maxi Basic M, 4x10, Neu
792321	TENA Pants Plus Basic L, 4x14, Neu
792322	TENA Pants Super Basic L, 4x12, Neu
792323	TENA Pants Maxi Basic L, 4x10, Neu
792324	TENA Pants Plus Basic XL, 4x12, Neu
792326	TENA Pants Plus Value XS, 4x14, Neu
792327	TENA Pants Plus Value S, 4x14, Neu
792328	TENA Pants Super Value S, 4x12, Neu
792329	TENA Pants Plus Value M, 4x14, Neu
792330	TENA Pants Super Value M, 4x12, Neu
792331	TENA Pants Maxi Value M, 4x10, Neu
792332	TENA Pants Plus Value L, 4x14, Neu
792333	TENA Pants Super Value L, 4x12, Neu
792334	TENA Pants Maxi Value L, 4x10, Neu
792335	TENA Pants Plus Value XL, 4x12, Neu
792336	TENA Pants Super Value XL, 4x12, Neu
792339	TENA Pants Plus XS 4x14p, INT
792414	TENA Pants Plus Small, 4x14 pcs
792415	TENA Pants Plus Small, 4x14p, INT, Ps
792417	TENA Pants Plus Small, 4x14p, JP, Ps
792434	TENA Pants PLUS Small, 4x14
792450	TENA Pants Plus Small 10pcs
792464	TENA Pants PLUS Small,4x14
792470	ORLYS Pants Noche P, 4x10
792509	TENA Pants PLUS Medium, 4x9
792510	TENA Pants PLUS M, 4x10, OTC Edition
792514	TENA Pants PLUS Medium, 4x14
792531	TENA Pants Plus M
792533	TENA Pants Plus, M, 4x9, int, CODE
792534	TENA Pants Plus, M, 4x14, IT CODE
792536	TENA Pants Original Plus M, 4x14p
792537	TENA Pants Extra M, 8x14pcs, NEU, NSW
792538	TENA Pants Plus M, 4x18
792539	TENA Pants Plus M,4x14pcs,Sou
792541	TENA Pants Plus M, 2x30p, EAST
792542	TENA Pants Plus M, 4x10p, OTC Edition
792543	TENA Pants Extra M, 4x10p, OTC Edition
792544	TENA Pants Extra M, 2x30p, EMEA

792547	TENA Pants Plus Classic M, 4x14p, NEU, IT
792548	TENA Pants Plus Medium, 4x14p, JP, Ps
792549	TENA Pants Plus Medium, 4x14p, INT, Ps
792564	TENA Pants PLUS Medium, 4x14, Neutral
792569	TENA Pants Plus Medium, 6x9p, INT
792571	Orlys Pants Noche M, 2x30p, ES
792574	TENA Pants Plus Medium, 4x14p, eC
792575	ORLYS Pants Noche M, 8x10, ES
792579	TENA Pants Plus M, 6x9, FR
792581	TENA Pants Plus Medium 12x9p, FR
792608	TENA Pants PLUS Large, 4x8
792609	TENA Pants Plus, L, 4x8, int, CODE
792610	TENA Pants Plus L, 4X10, OTC Edition
792611	TENA Pants Extra L, 8x10pcs, NEU, NSW
792613	TENA Pants Plus L, 4x14pcs, Sou
792614	TENA Pants PLUS Large, 4x14
792617	TENA Pants Plus L, 2x30p, EAST
792618	TENA Pants Plus L, 4x10p, OTC Edition
792619	TENA Pants Extra L, 4x10p, OTC Edition
792621	TENA Pants Extra L, 2x30 pcs, EMEA
792624	TENA Pants Plus Classic L, 4x14p, NEU, IT
792625	TENA Pants Plus Large, 4x14p, JP, Ps
792631	TENA Pants Plus L
792634	TENA Pants Plus, L, 4x14, IT CODE
792636	TENA Pants Plus L, 4x16
792638	TENA Pants Original Plus L, 4x14p
792645	TENA Pants Plus, L, 4x14, DE
792664	TENA Pants PLUS Large, 4x14, Neutral
792668	TENA Pants Plus Large, 6x8p, INT
792674	TENA Pants Plus Large, 4x14p, eC
792678	TENA Pants Plus L, 6x8, FR
792679	TENA Pants Plus Large 12x8p, FR
792681	Orlys Pants Noche G, 8x10p, ES
792682	ORLYS Pants Noche G, 8x10p, ES
792707	TENA Pants PLUS XL, 4x7
792712	TENA Pants Plus XL, 4x12 pcs
792713	TENA Pants Plus XL, 2x12, SRP
792715	TENA Pants Plus XL, 4x12p, INT, Ps
792717	TENA Pants Plus XL, 4x12p, JP, Ps
792734	TENA Pants Plus, XL, 4x12, Italy
792762	TENA Pants PLUS XL, 4x12
793100	TENA Pants Discreet L
793107	TENA Pants Discreet L
793300	TENA Pants Discreet, L
793412	TENA Pants Super Small, 4x12 pcs
793413	TENA Pants Super Small, 4x12p, INT, Ps
793414	TENA Pants Super Small, 4x12p, JP, Ps
793462	TENA Pants SUPER Small, 4x12
793470	ORLYS Pants Super Noche P, 4x10
793512	TENA Pants SUPER Medium, 4x12
793520	TENA Pants Super Medium, 4x12p, INT, Ps
793521	TENA Pants Super Medium, 4x12p, JP, Ps
793531	TENA Pants Super M

793534	TENA Pants Super, M, 4x12, IT CODE
793538	TENA Pants Super Medium, 4x10p, IT, CODE
793562	TENA Pants SUPER Medium, 4x12, Neutral
793570	ORLYS Pants Super Noche M, 4x10
793571	ORLYS Pants SuperNoche M, 8x10p, ES
793572	TENA Pants Night Super M, 4x10p, OTC, PS
793573	TENA Pants Night Super Medium, 2x30p, PS
793574	TENA Pants Night Super M,8x10,NEU,NSW,PS
793575	TENA Pants Night Super M,4x10,NEU,NSW,PS
793612	TENA Pants SUPER Large, 4x12
793614	TENA Pants Super Large, 4x12p, INT, Ps
793615	TENA Pants Super Large, 4x12p, JP, Ps
793631	TENA Pants Super L
793632	TENA Pants Super, L, 4x12, IT CODE
793634	TENA Pant Super Large, 4x10p, IT, CODE
793662	TENA Pants SUPER Larger, 4x12, Neutral
793670	ORLYS Pants Super Noche G, 8x10
793671	TENA Pants Night Super L,8x10,NEU,NSW,PS
793672	TENA Pants Night Super L, 4x10p, OTC, PS
793673	TENA Pants Night Super Large, 2x30p, PS
793674	TENA Pants Night Super L,4x10,NEU,NSW,PS
793712	TENA Pants SUPER XL, 4x12
793713	TENA Pants Super XL, 4x12p, INT, Ps
793732	TENA Pants SUPER XL, 4x12
793762	TENA Pants SUPER XL, 4x12
794510	TENA Pants MAXI Medium, 4x10
794512	TENA Pants Maxi Medium 4x10p, INT, Ps
794530	TENA Pants Maxi, M, 4x10, IT CODE
794532	TENA Pants Maxi Medium 4x8p, IT, CODE
794560	TENA Pants MAXI Medium, 4x10, Neutral
794610	TENA Pants MAXI Large, 4x10
794623	TENA Pants Maxi Large, 4x10p, INT, Ps
794630	TENA Pants Maxi, L, 4x10, IT CODE
794633	TENA Pants Maxi Large, 4x8p, IT, CODE
794660	TENA Pants MAXI Large, 4x10, Neutral
794760	TENA Pants Maxi XL, 4x10, neutral
794761	TENA Pants Maxi XL, 4x10p, INT
796512	TENA Pants Plus Night M, 4x12
796513	TENA Pants Plus Night Medium,4x16p, Mega
796612	TENA Pants Plus Night L, 4x12
796613	TENA Pants Plus Night Large,4x16p, Mega

Document Title Device Description TENA Pants Unisex	Date 2019-03-04
	Revision 1
Issued by Technical Article Manager, Åsa Lennersten, Cecilia Wängroth	

General description and intended use



TENA Pants Unisex is an assortment of unisex, underwear-like, disposable absorbent hygiene products, intended to be used by individuals suffering from moderate to heavy urine incontinence problems. The products can be used in a home-care environment or at institutions.

The main intended use of the product is that:

1. it shall absorb urine from incontinent individuals
2. it shall take care of faeces from incontinent individuals
3. it shall keep the skin dry

The assortment consist of the absorption levels Discreet, Normal, Plus, Super and Maxi. The sizes available in each asorption level are:

Unisex assortment:

Discreet M,L

Normal S,M,L,XL

Plus XXS, XS, S, M, L, XL

Super S, M, L, XL

Maxi M, L, XL

Content

The products consist of an absorbent part (inner part) enclosed in a pant part (outer part). The inner part consists of one or two cores made up of fluff pulp and super absorbent polymer (SAP). In parts of the assortment the cores have channels with less absorbing material and lengthwise crotch elastic threads in the centre. In other parts, the core is sealed with tissue or NW material. The core(s) are sandwiched between a liquid permeable nonwoven topsheet attached to a liquid permeable inlet

material (wadding/high loft), and a liquid non-permeable backsheet. The outer part consists of two separate webs, each made of two nonwoven layers with elastic threads glued in between, forming an elastic breathable material. The materials are joined together with glue or by ultra sonic welding.

The table below describes the function of the various components in the product.

Component	Function	Material
Top sheet	User comfort/keep skin dry	Non-woven
Transfer layer	Transport urine	High loft non-woven / Wadding
Absorbent core	Absorb and store urine and faeces	Fluff pulp, superabsorbent polymer
Core wrap*	Sealing of absorption core	Tissue or non-woven material, where tissue consists of ECF or TCF bleached kraft pulp
Back sheet	Prevent leakage, supporting the absorption core	Polyethylene (PE) or Polypropylene (PP) film
Pant chassis	Underwear design, correct placement of absorption core	Elastic material made of nonwoven and elastic threads
Standing gather	Prevent leakage sideways	Non-woven
Elastic threads	User comfort, prevent leakage, shape of the product	Synthetic rubber
Adhesive	Joining materials /lamination	Blend of polymers (hotmelt)
Colors, printing inks	Top sheet and back sheet may be printed /colored for information and improved looks.	Printing inks, pigments
Disposal tape (parts of assortment)	Hygienic disposal of product	Plastic tape with glue
Bags	Protection of product during storage and transportation.	Polyethylene (PE) film
Boxes	Storage and transportation	Pulp, often recycled fibres

* : TENA Pants Normal and Plus Unisex (made in Poland and Canada)

Material description

Nonwoven

Spunbond nonwoven is a thin textile like material. It is made from continuously formed polypropylene fibers bound together by heat. Polypropylene is a common polymer material made from oil or natural gas.

High loft nonwoven

High loft nonwoven is a thin textile like material. It is made from continuously formed polypropylene fibres bound together by heated air. Polypropylene is a common polymer material made from oil or natural gas.

Fluff pulp

Fluff pulp is made from wood, and is renewable material. The fluff pulp is ECF (elementary chlorine free) bleached, i.e. no chlorine gas is used. Almost all fluff pulp world-wide is ECF.

Tissue

Tissue is made from pulp, 100% ECF or TCP bleached pulp and is used as core wrapping/sealing or carrier in production.

Superabsorbent polymer (SAP)

The superabsorbent polymer consists of particles which can absorb and hold large amounts of urine/liquid. The polymer used is cross-linked polyacrylate salt.

Polyethylene/Polypropylene film (PE/PP)

Polyethylene/polypropylene is a common plastic material made from oil or natural gas.

Elastic threads

Synthetic elastic polymer (lycra) thread.

Adhesives

Hotmelt adhesives are blends of polymers (mainly polyolefin or styrene block-copolymers) and hydrocarbon resins (only of synthetic origin).

Printing ink, pigments

Pigments in printing ink does not contain any metals or metal compounds of concern.

Tape

A composite made of polypropylene film, partly siliconized and coated with pressure sensitive adhesive.

Polyethylene (bags)

The polyethylene bags are recyclable.

Pulp (cardboard boxes)

This pulp is normally unbleached. 50-100% of the material comes from recycled fibers.

Regulatory Information

TENA Pants Unisex is a Medical Device Class I according to Rule 1 of Annex VIII of Medical Devices Regulation (EU) 2017/745, in combination with the intended use described by Essity Hygiene and Health AB, and carry the CE mark.

This classification of TENA Pants Unisex has not been changed from the classification according to the former legislation, Medical Device Directive 93/42/EEC.

The GMDN, Global Medical Device Nomenclature, code is 41588, Incontinence pants, single-use, "a trouser-like device worn by a person suffering from incontinence to collect

urine and faeces. This device is for single-use and may require a single-use liner used inside the pants, (see: Incontinence pants, liner)".

Each consumer pack are labeled with indication for being a medical device, by text in each market language.

Product safety

Biological evaluation of the product and its components is carried through according to the International standard ISO 10993, Biological evaluation of medical devices.

Clinical investigation according to ISO 14155 are usually not performed on this type of product. Clinical evaluation is always done, and together with a very long history of safe use shows that our system for ensuring product safety is sufficient.

The products are free from natural rubber latex, colophonium, PVC and phthalates. They do not contain any substances that are generally recognized as allergens. Nor do these products contain any substances that are carcinogenic, mutagenic or toxic to reproduction as defined in European Directive 1999/45/EC (CLP) and Regulation (EU) 453/2010 (REACH).

The fluff pulp does not contain any optical brighteners and the ink pigments used for print on the products does not contain any metals or metal compounds of concern.

There is no need for the products to be sterile. The products are intended to be used in the intimate regions of the body which are, by nature, colonized by millions of microorganisms, and intended for collection of urine and faeces. Even if the products are contaminated by microorganisms before use, these microorganisms will not thrive in the absorbent incontinence products due to:

- a low moisture content
- absence of nutrients in the products
- the intended use of the products being single use, thus no risk of transmission of microorganisms from other users

Storage and handling conditions, expire date

There are no specific legislative requirements for storage conditions for absorbent hygiene products for incontinence care.

In the General Safety and Performance Requirements (Annex I in Medical Devices Regulation (EU) 2017/745) under sections 23.2 (i) and (k) regarding labeling is found:

(i) An unambiguous indication of the time limit for using /.../ the device safely /.../ where this is relevant

(k) an indication of any special storage and/or handling condition that applies

Absorbent hygiene products in general do not have any specific shelf life time when it comes to safety. The absorbent hygiene products consist mainly of materials of wood pulp, polyethylene, polypropylene and polyacrylate polymers. The absorption properties of the products are very stable over time, but there are some materials as glue, elastics etc. where the mechanical properties might be decreased over time. The degradation of ingoing materials will not cause any hazardous substances being formed. The best before date is 36 months after production. Three years is not any **expire date** but a **best before date**. Post market surveillance data has showed us that the safety and the main functions of the products will remain much longer than this.

This is valid under normal storage and handling conditions and in unbroken packages. We also recommend our products not being stored together with chemicals or substances with strong smell to avoid adherence of smell.

Absorbent hygiene products shall be protected from extremes of temperature and weather during storage and transport.

Waste

These absorbent hygiene products do not contain any ingredients or materials that are classified as hazardous to humans or the environment during post-consumer waste treatment.

As per European List of Waste (Commission Decision 2000/532/EC) these products are classified as a non-hazardous waste fraction and need not be disposed of in any specified way. The List of Waste code is: 18 01 04 "wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)".

There may be generation of greenhouse gases during breakdown of any organic material for example on a landfill. According to European legislation and common sense landfilling should be avoided. Modern waste technologies can make the products suitable for all common waste handling systems; however it will be the local circumstances and infrastructure that determine which one that will be used.

All ingoing materials are optimized for its use, also in amount of the material used in the products to decrease the environmental impact.

Manufacturer and certification

Essity Hygiene and Health AB, S-405 03 Gothenburg, Sweden is the legal manufacturer as defined in Medical Devices Regulation (EU) 2017/745 for TENA Pants Unisex placed on the EEA market.

Essity Hygiene and Health AB is certified according to current ISO 13485 Quality Management System for Medical Devices. The production units for TENA Pants Unisex are certified per ISO 9001 (quality).

The Competent Authority for Essity Hygiene and Health AB's medical devices is the Swedish Medicinal Products Agency. With the MPA the medical devices are notified, until the European database for registration of medical devices per MDR is established.

Document scope

The European Directive 1999/45/EC (CLP) defines hazardous preparation and states the requirements for classification, packaging and labelling of dangerous preparations. The information within this Directive indicates that this medical device does not require a safety data sheet. Therefore a Safety Data Sheet, SDS, according to Regulation (EU) 453/2010 (REACH) is not issued for the product concerned in this document. Instead is here collected information regarding quality and safety aspects of the product.

Technical Data for TENA Pants, Unisex assortment

Average value

EC DECLARATION OF CONFORMITY

Essity Hygiene and Health AB

SE-405 03 Göteborg

Sweden

hereby declares that the medical devices TENA Bed intended for incontinence care according to the enclosed article list, fulfill the provisions of Council Directive 93/42/EEC of 14 June 1993, amended as relevant.

The products are classified as medical devices class I according to said Directive and the GMDN code is 61850 (formerly 12467).

The conformity assessment is carried out in accordance with Annex VII of the Medical Device Directive 93/42/EC.

The products are hereby also in conformity with all relevant parts of Swedish legislation regarding requirements of the Medical Devices Directive and corresponding regulation from Medical Products Agency. The articles are notified with Swedish competent authority, Medical Products Agency.

Mölnadal, on May 19th, 2020



Essity Hygiene and Health AB
405 03 GÖTEBORG
SWEDEN

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

This Declaration of Conformity is valid until replaced with a new version and no longer than January 31st, 2021. It is managed by SCR GBIS Certified Products Department - Hygiene

Seat: Göteborgs kommun. Registration number: SE556007-2356

Essity Hygiene and Health AB
SE-405 03 GÖTEBORG
Sweden

Visitors' address:
Mölnäls Bro 2, Mölnäls
Phone: +46 31 746 00 00
www.essity.com

TENA Bed Assortment

Article number	Article
211417	TENA Bed Normal 6x15 pcs
770027	TENA Basic Bed 60x60
770037	TENA Bed Normal 60x60
770038	TENA Bed Normal 60x90
770039	TENA Bed Normal 60x60 10p
770040	TENA Bed Normal 60x90 10p
770044	TENA Bed Normal 60x60
770045	TENA Bed Normal 60x60
770046	TENA Bed Normal 60x90
770047	TENA Bed Normal 60x90
770048	TENA Bed Original 60x60
770049	TENA Bed Original 60x90
770054	TENA Bed Plus Secure Zone, 60x60, 24x5p, OTC Edition
770055	TENA Bed Plus Secure Zone, 60x90, 24x5p, OTC Edition
770056	TENA Bed Normal 60x60 24x5p
770057	TENA Bed Normal 60x90 24x5p
770064	TENA Bed Plus 60x60, 24x5p, OTC Edition
770065	TENA Bed Plus 60x90, 24x5p, OTC Edition
770068	TENA Bed Normal 60x90 10x10pcs INT
770069	TENA Bed Normal 60x90 5x30pcs INT
770071	TENA Bed Normal 60x90
770073	TENA Bed Normal 60x90
770077	TENA Bed Normal 90x180 6x30 pcs INT
770078	RINACARE Underpad 60x90, 5x30pcs
770079	RINACARE Underpad 60x90, 10x10pcs
770100	TENA Bed Plus Secure Zone 60x60, 4x30p
770103	TENA Bed Plus Secure Zone 60x90, 4x20p
770104	TENA Bed Plus Secure Zone 60x90, 4x30p
770108	TENA Bed Plus Secure Zone 90x80, 4x20p N
770109	TENA Bed Plus Secure Zone 60x60, 4x30p N
770111	TENA Bed Plus Secure Zone 60x90, 4x30p N
770113	TENA Bed Plus Secure Zone 60x40, 6x30p
770114	TENA Bed Plus Secure Zone 60x40, 6x30p N
770115	TENA Bed Plus Secure Zone 60x75, 3x30p
770116	TENA Bed Plus Secure Zone 60x75, 3x30p N
770118	TENA Bed Plus 60x40
770119	TENA Bed Plus 60x60
770120	TENA Bed Plus 60x90
770121	TENA Bed Plus 60x75
770122	TENA Bed Plus, 60x40
770124	TENA Bed Plus 60x60, 4x30p
770125	TENA Bed Plus 60x90, 4x30p
770130	TENA Bed Plus Secure Zone 60x90 10x10p INT
770131	TENA Bed Plus SecureZone 60x75, 4x25pcs N
770134	TENA Bed Plus Secure Zone 60x90 5x30pcs INT
770200	TENA Bed Super Secure Zone 60x90, 2x30p

770202	TENA Bed Super Secure Zone 60x60, 4x30p
770207	TENA Bed Super Secure Zone 60x60, 4x30p N
770208	TENA Bed Super Secure Zone 60x90, 2x30p N
770210	TENA Bed Super SecureZone 60x90, 3x26p N
771000	TENA Bed Plus 60x60
771102	TENA Bed PlusWing 180x80 Secure Zone, 4x20p IT
771103	TENA Bed PlusWing 180x80 Secure Zone, 4x20p N
771170	Tena bed Normal 60x60
771171	Tena bed Normal 60x90
772531	TENA Bed Super 60x75
772532	TENA Bed Super 60x90
772534	TENA Bed Super 60x75, 4x28pcs IT
773610	TENA Bed Plus 60x90
773620	TENA Bed Plus Secure Zone 60x90, 4x20p
773680	TENA Bed Plus 60x90
773800	TENA Bed Super 60x90

EC DECLARATION OF CONFORMITY

Essity Hygiene and Health AB

SE-405 03 Göteborg

Sweden

hereby declares that the medical devices TENA Slip intended for incontinence care according to the enclosed article list, fulfill the provisions of Council Directive 93/42/EEC of 14 June 1993, amended as relevant.

The products are classified as medical devices class I according to said Directive and the GMDN code is 11239.

The conformity assessment is carried out in accordance with Annex VII of the Medical Device Directive 93/42/EC.

The products are hereby also in conformity with all relevant parts of Swedish legislation regarding requirements of the Medical Devices Directive and corresponding regulation from Medical Products Agency. The articles are notified with Swedish competent authority, Medical Products Agency.

Mölnadal, on June 12th 2020

Essity Hygiene and Health AB
405 03 GÖTEBORG
SWEDEN



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

This Declaration of Conformity is valid until replaced with a new version and no longer than January 31st, 2021. It is managed by SCR GBIS Certified Products Department - Hygiene

Seat: Göteborgs kommun. Registration number: SE556007-2356

Essity Hygiene and Health AB
SE-405 03 GÖTEBORG
Sweden

Visitors' address:
Mölnadal Bro 2, Mölnadal
Phone: +46 31 746 00 00
www.essity.com

TENA Slip Assortment

Article number	Article
68010	TENA Slip Plus XL 4x15
68011	TENA Slip Super XL 4x15
100267	TENA Slip Super Medium Ps 60x1pcs A
100268	TENA Slip Super Large Ps 60x1pcs A
211308	TENA Slip Original Plus Small 4x30pcs
211309	TENA Slip Original Plus Medium 4x30pcs
211310	TENA Slip Original Plus Medium 8x10pcs
211311	TENA Slip Original Plus Large 4x30pcs
211312	TENA Slip Original Plus Large 8x10pcs
211314	TENA Slip Confioair Plus Small 4x30 pcs
211315	TENA Slip Confioair Plus Medium 4x30 pcs
211316	TENA Slip Confioair Plus Medium 8x10 pcs
211317	TENA Slip Confioair Plus Large 4x30 pcs
211318	TENA Slip Confioair Plus Large 8x10 pcs
211328	Tena Slip Original L 4x30pcs
211329	Tena Slip Original M 4x30pcs
211336	SLIPAD Super Large 2x40 pcs, ES
211337	TENA Slip Confioair Plus Large 30x2 pcs
211338	TENA Slip Confioair Plus Medium 30x2 pcs
211339	TENA Slip Plus Original Extra Large 30 pcs
211340	TENA Slip Elastico Plus Small 2x40pcs ES
211341	TENA Slip Original Super Medium, Greece 6x10 pcs
211342	TENA Slip Original Super Large, Greece 6x9 pcs
211343	TENA Slip Original Super X Large, Greece 6x8 pcs
211344	TENA Slip Confioair Plus Medium 4x15 pcs
211345	TENA Slip Confioair Plus Large 4x15 pcs
211357	TENA Slip Confioair Plus XL 2x30 pcs
211400	TENA Slip Classic TXT Plus Medium 4x30 pcs
211402	TENA Slip Classic TXT Plus Large 4x30 pcs
211403	TENA Slip Classic PE Plus Medium 4x30 pcs
211404	TENA Slip Classic PE Plus Large 4x30 pcs
211409	TENA Slip Classic Textile Medium 12x8 pcs
211413	TENA Slip Classic Textile Large 12x7 pcs
211414	TENA Slip Classic PE Plus Small 4x30 pcs
211426	TENA Slip Original Plus Small 3x30pcs INT
211450	TENA Slip Basic Plus Medium, 4x30p
211451	TENA Slip Basic Plus Large, 4x30p
211452	TENA Slip Basic Super Medium, 4x25p
211453	TENA Slip Basic Super Large, 4x25p
211454	TENA Slip Complete Plus Medium 3x30p
211456	TENA Slip Complete Plus Large 4x30p
211457	TENA Slip Complete Super Medium 3x30p
211458	TENA Slip Complete Super Large 4x30p
211459	TENA Slip Complete Care Plus Medium 3x30p
211460	TENA Slip Complete Care Plus Large 4x30p
211462	TENA Slip Complete Care Super Medium 3x30p
211463	TENA Slip Complete Care Super Large 4x30p
211540	TENA Slip Elastico Plus Medium 2x40pcs ES

211640	TENA Slip Elastico Plus Large 2x40pcs ES
211940	TENA Slip Elastico Super Medium 2x40pcs ES
212024	TENA Slip Original Maxi Medium
212040	TENA Slip Elastico Super Large 2x40pcs ES
212100	TENA Slip Classic Plus M 8x10 pcs
212101	TENA Slip Classic Plus M 4x15
212102	TENA Slip Classic Plus Medium 4x30 pcs
212103	TENA Slip Classic Plus L 8x10 pcs
212104	TENA Slip Classic Plus L 4x15
212105	TENA Slip Classic Plus Large 4x30 pcs
212106	TENA Slip Original Plus XL 3x30 (EU Design)
212124	TENA Slip Original Maxi Large
212130	TENA Slip Original Plus Medium
212230	TENA Slip Original Plus Large
212330	TENA Slip Original Super Medium
212430	TENA Slip Original Super Large
710005	TENA Slip Super medium
710030	TENA Slip Super Small
710157	Libero Junior
710256	TENA Slip Plus Medium 4x20pcs
710356	TENA Slip Plus Large 4x20pcs
710430	TENA Slip Plus Extra Small
710449	TENA Slip Active Fit Plus XS 3x30pcs
710454	TENA Slip Premium Plus Medium 4x30 pcs
710455	TENA Slip Premium Plus Large 4x30 pcs
710457	TENA Slip Premium Plus XL 4x30 pcs
710458	TENA Slip Plus M Non Breathable 6x8pcs RU
710459	RINACARE Slip TXT Small 4x30p
710460	TENA Slip Elastico Plus M 4x20p, ES, Proskin
710461	RINACARE Slip TXT Medium 4x30p
710462	RINACARE Slip TXT Large 4x30pcs
710463	RINACARE Slip TXT XL 4x30pcs
710464	RINACARE Slip TXT Large 12x7pcs
710465	RINACARE Slip TXT Medium 12x8p
710501	TENA Slip Maxi medium
710511	TENA Slip Maxi medium
710521	TENA Slip Ultima Medium
710522	TENA Slip Ultima Medium 3x21pcs, INT NEU
710530	TENA Slip Plus Small
710532	TENA Slip Plus Small 3x30 pcs, UA
710549	TENA Slip Active Fit Plus S 3x30pcs
710558	TENA Slip Plus L Non Breathable 6x8pcs RU
710560	TENA Slip Elastico Plus L 4x20p, ES, Proskin
710600	TENA Slip ProSkin Plus Medium 3x30p
710605	TENA Slip ProSkin Plus Medium 4x10p
710606	TENA Slip Plus Medium 3x30 pcs M cC, UA
710610	TENA Slip Plus Medium OTC Edition
710611	TENA Slip Plus Medium 6x10 pcs, UA
710621	TENA Slip Ultima Large
710622	TENA Slip Ultima XL 3x18pcs
710623	TENA Slip Ultima Large 3x21pcs, INT NEU
710626	TENA Slip Elastico Plus S 4x20p, ES, ProSkin

710630	TENA Slip Plus Medium
710634	TENA Slip Plus Medium 3x30 pcs, UA
710649	TENA Slip Active Fit Plus M 3x30pcs
710700	TENA Slip ProSkin Plus Large 4x30p
710701	TENA Slip ProSkin Plus Large 4x10p
710702	TENA Slip Plus Large 4x30 pcs M cC, UA
710710	TENA Slip Plus Large OTC Edition
710713	TENA Slip Plus Large 6x10 pcs, UA
710721	TENA Slip Active Fit Ultima M 3x21pcs
710730	TENA Slip Plus Large
710732	TENA Slip Plus Large 3x30p
710734	TENA Slip Plus Large 3x30 pcs, UA
710749	TENA Slip Active Fit Plus L 3x30pcs
710821	TENA Slip Active Fit Ultima L 3x21pcs
710824	TENA Slip Maxi Small
710849	TENA Slip Active Fit Maxi S 3x24pcs
710910	TENA Slip Maxi Medium
710924	TENA Slip Maxi Medium
710928	TENA Slip Maxi Medium 3x24 pcs, UA
710949	TENA Slip Active Fit Maxi M 3x24pcs
711004	TENA Slip Premium Super Small 3x30pcs
711005	TENA Slip Premium Super Medium 3x28pcs
711006	TENA Slip Premium Super Medium 6X10pcs
711007	TENA Slip Premium Super Large 3x28 pcs INT
711008	TENA Slip Premium Super Large 6x10pcs
711009	TENA Slip Premium Maxi Medium 3x24pcs, INT
711010	TENA Slip Maxi Large
711011	TENA Slip Premium Maxi Large 3x24pcs, INT
711012	TENA Slip Premium Plus Medium 6x10pcs
711013	TENA Slip Premium Plus Medium 3x30pcs
711016	TENA Slip Premium Plus Large 3x30pcs
711017	TENA Slip Premium Plus Large 6x10pcs
711020	TENA Slip Premium Plus Small 3x30pcs
711021	TENA Slip Plus XL 3x30 pcs
711022	TENA Slip Maxi Large
711023	TENA Slip Super XL 3x28 pcs
711024	TENA Slip Maxi Large
711026	TENA Slip Maxi XL 3x24 pcs
711027	TENA Slip Premium Super Night M 4x30p TR, B2
711029	TENA Slip Premium Super Night L 4x30p TR, B2
711030	TENA Slip Premium Plus Small, 4x30 pcs
711032	TENA Slip Maxi Large 3x24p
711033	TENA Slip Maxi Large 3x24 pcs, UA
711049	TENA Slip Active Fit Maxi L 3x22pcs
711130	TENA Slip Super Small
711201	TENA Slip ProSkin Super Medium 3x30p
711206	TENA Slip ProSkin Super Medium 4x10p
711207	TENA Slip Super Medium 3x30 pcs M cC, UA
711210	TENA Slip Super Medium OTC Edition
711211	TENA Slip Super Medium 6x10 pcs, UA
711225	TENA Slip Super Medium No3
711228	TENA Slip Super Medium

711230	TENA Slip Super Medium
711233	TENA Slip Super Medium 3x30 pcs, UA
711400	TENA Slip ProSkin Super Large 4x30p
711401	TENA Slip ProSkin Super Large 4x10p
711402	TENA Slip Super Large 4x30 pcs M cC, UA
711410	TENA Slip Super Large OTC Edition
711411	TENA Slip Super Large 6x10 pcs, UA
711425	TENA Slip Super Large No4
711428	TENA Slip Super Large
711430	TENA Slip Super Large
711431	TENA Slip Super Large 3x28p
711433	TENA Slip Super Large 2x30 pcs, UA
711460	TENA Slip Elastico Plus M 4x20p, ES, Proskin
711560	TENA Slip Elastico SuperL 4x20p, ES, Proskin
711824	TENA Slip Maxi Medium 3x24p
711928	TENA Slip Super Medium 3x28p
711930	TENA Slip Super Small 3x30p
712030	TENA Slip Maxi Small 3x24p
712130	TENA Slip Plus Small 3x30p
712230	TENA Slip Plus Medium 3x30p
714240	TENA slip Super medium
714328	TENA slip Super Large, 28-pack
714340	TENA slip Super large
750521	TENA Slip Basic Value Plus S
750528	TENA Slip Basic Value Plus M
750529	TENA Slip Basic Value Plus L
750531	TENA Slip Basic Value Super M
799900	TENA Slip Elastico Plus M
799901	TENA Slip Elastico Plus L
799902	TENA Slip Elastico Super M
799903	TENA Slip Elastico Super L
799904	TENA Slip Value Plus Small
799905	TENA Slip Value Plus Medium
799906	TENA Slip Value Plus Large
799907	TENA Slip Value Super Small
799908	TENA Slip Value Super Medium
799909	TENA Slip Value Super Large
799910	TENA Slip Value Maxi Medium
799911	TENA Slip Value Maxi Large
799918	TENA Slip Elastico Plus Small
799919	TENA Slip Original Classic Plus, S
799920	TENA Slip Original Classic Plus, M
799921	TENA Slip Original Classic Plus, L
799922	TENA Slip Original Classic Super M
799923	TENA Slip Original Classic Super L
799924	TENA Slip Original Classic Maxi M
799925	TENA Slip Original Classic Maxi L