



A MEDIQ COMPANY

Device Product Description
Technical File Section 6
Revision 06/20.11.2025

Absorin® Comfort, Classic and Underpads

		In function of:	Signature	Date
Prepared by	Federica Russo	<i>Regulatory Affairs Specialist</i>		
Reviewed by	Anouar Chamakhi	<i>Associate Category & Product Development Manager Absorbing incontinence</i>		
Approved by	Warsha Baboelal	<i>QA/RA Manager</i>		

History of changes

Revision	Reason / Summary of change	Name	Date
01	First release	Tiago Silva, RA officer	20-07-2018
02	Underpads and Absorin Classic added. Product specifications updated.	Tiago Silva, RA officer	06-09-2019
03	Slip Ultra XL, Pants Plus XXL and Pants Super XXL added to portfolio. MDR compliance update.	Tiago Silva, RA officer	18-12-2020
04	Classification under UK MDR 2022 added. Device information updated. New claims added for Finette.	Federica Russo, RA Specialist	30-10-2024
05	Update according to new template and changes in the portfolio reflecting NPD 2024-006, NPD 2024-05, NPD 2024-525, NPD2024-524, NPD 2025-002, NPD 2025-017, NPD 2024-023	Federica Russo, RA Specialist	07-05-2025
06	Update according to changes in the portfolio reflecting NPD 2025-016, NPD 2025-022	Federica Russo, RA Specialist	20-11-2025

Table of Contents

6.1	Product Description	4
6.1.1	Intended Use, claims and precautions	4
6.2	Product specification.....	9
6.2.1	Product Classification	13
6.2.2	Packaging specifications.....	14
6.2.3	Storage conditions	14
6.2.4	Shelf life.....	14
6.2.5	Requirements for installation and servicing.....	15

6 Device Information

Product: Absorin® Comfort, Classic and Underpads

Risk Class: Rule I, Class I

Basic UDI-DI: 18756INCCT0401JS

EMDN Code: T0401

GMDN Code: 61848

Regulatory status: Absorin® Comfort, Classic and Underpads is CE-marked and has been on the market for approximately 12-17 years..

Legal Manufacturer Name	Medeco B.V.
Address	Brandpuntlaan Zuid 14, 2665 NZ Bleiswijk, The Netherlands
SRN	NL-MF-000001628

Subcontractor Name	Ningbo KeRui Hygiene Product Co., Ltd (Greencare)
Address	Chunhu town, Ningbo,315000,China
Website	http://www.recowater.cn

Subcontractor Name	LiveDo USA Inc.
Address	4925 Lamm Road Wilson, NC 27893
Website	https://www.livedousa.com/

Subcontractor Name	Ontex BVBA
Address	<i>Absorin Pants & Slimfit</i> - Genthof 5 - 9255 Buggenhout Belgium <i>Absorin Slip & Mincy</i> - Quai du Rivage, F 62119, DOORGES, France <i>Absorin Level 2, Absorin Finette Mini & Mini Plus</i> - Przedsiębiorców 6, 97-500 Radomsko, Poland <i>Absorin Finette Maxi Night</i> - Contrada Cucullo, 66026 Ortona CH, Italy <i>Absorin Super</i> - Contrada Cucullo, 66026 Ortona CH, Italy
Website	http://www.ontexglobal.com/

Subcontractor Name	S.I.Cell S.p.A.
Address	Via Occhiobello, 625/2 I-45024 Fiesse Umbertiano (RO) ITALIA
Website	https://www.sicell.it/

Subcontractor Name	A.M.D. SAS
Address	1111 rue Pablo Picasso – Parc de la Chêne 62320 ROUVROY – France
Website	www.amd-incontinence.com

Subcontractor Name	Viecura Medical Group Limited
Address	Building 14, No. 2058, Haizang West Road, Luzhi Town, Wuzhong District, Suzhou City, Jiangsu Province, China
Website	Home - Viecura Group

Subcontractor Name	Fujian Dashan Paper Co.,Ltd. (Nanteen)
Address	No.1553,Kailin Road, Taiwanese investment industrial area, Quanzhou,China 32212
Website	HOME nanteen

6.1 Product Description

Urinary incontinence (UI) is a condition defined by any uncontrolled leakage of urine. It affects both male and female population, and the natural causes justify its wide prevalence. Besides being associated with ageing, it can have a broad variety of origins. It was observed as a side effect of medication, a result of a fall, diabetes, labour, prostate enlargement, etc. Faecal incontinence consists of a lack of control over defecation. Although it's a condition less prevalent than urinary incontinence, it's believed it is still common, but under-reported. The list of causes is extensive: Structural anorectal abnormalities, neurological disorders, constipation, inflammatory bowel diseases, etc.

Because of the uncomfortableness and stress associated, both conditions have a significant impact on the quality of life. Several medical devices have been developed to attenuate the distress and enable the patients to live more normally. Absorbent products are widely consumed for that purpose. They can easily be found in different formats as slips, pants, pads, T-Fit systems, etc. They are disposable devices, and usually not intended to be used for more than 24 hours. They are often presented with different levels of absorbency, to meet the diverse needs of the patients.

Medeco B.V. offers a broad variety of products in the field of incontinence:

Absorin® Comfort	
Finette	Insert pad designed to be discreet and invisible to wear with elastic underwear.
Level 2	Absorbent pad, shaped to fit well against the male body.
Mincy	Anatomically shaped pad, specially designed for men, combining comfort with security.
Sanette*	Anatomically shaped absorbent pad that can be worn with elastic underwear or with Absorin® Fix pants.
Pants	Absorbent pad and underpants in one, suitable for active people who seek extra protection.
Slip	One-piece, absorbent dressing with four fixation strips.
T-Fit	One-piece absorbent pad with a hip belt that can be adjusted to the size of the user.
Underpad	Absorbent pad for mattress protection.

Device Product Description
Absorin® Comfort, Classic and Underpads
Revision 06/20.11.2025



Washable Underpad	Washable absorbent pad for mattress protection.
--------------------------	---

*Absorin® Comfort Sanette is distributed in Switzerland under the name Absorin® Comfort.

Absorin® Classic	
Inlay Midi	Rectangle shaped inlay extra absorbing, without fixture strip.
Inlay Maxi	

Device Product Description
Absorin® Comfort, Classic and Underpads
Revision 06/20/11.2025

6.1.1 Intended Use, claims and precautions

Absorin® Comfort			
Product	Intended Use	Claims	Precautions
Finette	- For women; - Mild to moderate urine loss and light faecal loss; - It must be used with tight elastic underwear; - A broad adhesive strip helps to fixate it.	- Fast absorption - Skin comfort	Single use.
Level 2	- For men; - Mild to moderate urine loss; - It remains in place thanks to a long, broad adhesive strip; - It must be worn with elastic, tight underwear	- Fast dry - Cotton feel - Men	Single use.
Mincy	- For men; - Mild to moderate urine loss; - It must be worn with elastic, tight underwear	- Dry feeling and odourless - Absorbs urine quickly neutralising the odour - Feels like cotton	Non-washable; Single use.
Sanette (distributed in Switzerland as Absorin® Comfort)	- Unisex; - Moderate to heavy urine loss and light faecal loss; - It can be worn with tight, elastic underwear; - A urine colour indicator tells the user when it is time to change the slip.		

Device Product Description
Absorin® Comfort, Classic and Underpads
Revision 06/20.11.2025

Pants	- Unisex; - Mild to moderate urine loss; - It can be worn as normal underwear.	- Fast absorption - Y-Core technology - Skin comfort - Unisex	
Slip	- Unisex; - Heavy urine and faecal loss during day and night; - Four strips fix it to the body; - A urine colour indicator tells the user when it is time to change the slip.	- Fast dry - Cotton feel - Unisex	Non-washable; Single use.
T-Fit	- Unisex; - Moderate to heavy urine and faecal loss; - Its hip belt can be adjusted to the size of the user; - A urine colour indicator tells the user when it is time to change the slip		
Underpads	- For mattress protection.	- Textured - Cotton feel - Unisex	
Washable underpad	- For mattress protection.	- High absorbance	Do not use bleach; Do not iron; Washable up to 90°C
Bariatric	- Unisex	- Fast dry - Cotton feel	Non-washable; Single use.

Device Product Description
Absorin® Comfort, Classic and Underpads
Revision 06/20.11.2025



Absorin® Classic			
Product	Intended Use	Claims	Precautions
Inlay Mini	- Unisex; - Suitable for light to moderate incontinence; - To wear with normal tight-fitting underwear or with Absorin® Fix Pants.	Latex free	Non-washable; Single use.
Inlay Maxi			

-

Device Product Description
Absorin® Comfort, Classic and Underpads
Revision 06/20.11.2025

6.2 Product specification

The Absorin® Comfort, Classic and Underpads are available in the following sizes:

Absorin® Comfort							
Product		REF	SAP Article number	Size	Inner box pcs	Boxes/outer carton	Supplier
Finette	Ultra Mini	1051 6200	3014426	19x7,5	28	12	Ontex
	Mini	10516206	3069420	22x8,5	20	12	
	Mini Plus	10516211	3069365	25x8,5	14	12	
	Normal	1051 7215	3073209	27x10	14	12	
	Extra	1051 7225	3073210	34x11,5	14	12	
	Super	1051 7235	3073211	34x11,5	16	12	
	Maxi	1051 7245	3073212	37x11,5	14	24	
	Maxi Night	10516256	3071483	50x20	30	4	
Level 2	-	10516601	3068771	30,5x18,5	10	16	A.M.D.
Mincy	Light	6400	3026352	24x8	28	8	
	Normal	6500	3026383	41x8	28	8	
Sanette	Day Light	1051 7308	3035714	61x32/28	20	4	
	Day	1051 7310	3035738	70x36/30	20	4	
	Day Extra	1051 7320	3035739	70x36/30	20	4	
	Night	1051 7330	3036311	70x36/30	20	4	
	Heavy	1051 7340	3036313	70x36/30	20	4	
	Ultra	1051 7350	3036314	70x36/30	20	4	
Pants	Slimfit	M	1051 1231	3070868	69x68	10	Ontex
		L	1051 1241	3070869	75x78	10	
		M	1325-A	3072121	78x68	14	

Device Product Description
Absorin® Comfort, Classic and Underpads
Revision 06/20.11.2025

		L	1335-A	3072123	86x78	14	8	Livedo
		XL	3065605	3065605	90x92,5	14	4	
	Fit	S	1051 1315	3014416	78x58	14	8	
		M	10611325	3072124	78x68	14	8	
		L	10611335	3072125	86x78	14	8	
		XL	10611345	3072126	90x92,5	14	8	
	Super	S	10531265	3068770	60x90	20	4	
		XXL	10531305	3059022	165x205	11	44	
	Plus	XS	1051 1205	3014412	78x56	20	4	Ontex
		XXL	10511255	3059021	102x98	12	48	
	Super	M	10531275	3065607	78x68	14	8	
		L	10531285	3065608	86x78	14	8	
		XL	10531295	3065609	90x92,5	14	4	
Slips	Day	XS	0808-A	3013999	52x21/25	14	12	
		M	0720-A	3013961	63x30/28	28	3	
		L	0730-A	3013963	72,5x30/28	28	4	
		XL	0840-A	3014065	72,5x30,5	20	4	
	Night	S	0815-A	3014009	56x30/33	14	8	
		M	0822-A	3014037	63x30/28	28	3	
		L	0832-A	3014055	72,5x30,5	28	3	
		XL	0842-A	3014067	72,5x30,5	14	4	
	Heavy	S	0910-A	3014087	70x53	20	4	
		M	0920-A	3014093	80-68	20	3	

Device Product Description
Absorin® Comfort, Classic and Underpads
Revision 06/20.11.2025

	Ultra	L	0930-A	3014097	98x80	20	3	
		XL	0940-A	3014099	98x85	14	4	
		M	1022-A	3014373	80-68	15	3	
		L	1032-A	3014379	98x80	15	3	
		XL	1042-A	3060337	98x85	14	4	
T-Fit	Day	M	1051 9125	3036689	80x36	15	4	S.I.Cell
		L	1051 9135	3036704	84x40	15	4	
		XL	1051 9825	3014442	90x40	15	4	
	Night	S	1051 9025	3014443	70x36	15	4	
		M	1051 9325	3036697	80x36	15	4	
		L	1051 9335	3036706	84x40	15	4	
		XL	1051 9835	3014446	90x40	15	4	
	Heavy	S	1051 9035	3014447	70x36	15	4	
		M	1051 9725	3036698	80x36	15	4	
		L	1051 9735	3036707	84x40	15	4	
		XL	1051 9845	3014449	90x40	15	4	
	Ultra	M	1051 9925	3036730	80x36	15	4	
		L	1051 9935	3036731	84x40	15	4	
Underpad	Normal	60x40	1053 4060	3069463	60x40	30	9	Greencare
		60x60	1053 6060	3069465	60x60	30	4	
		60x90	1053 6090	3069467	60x90	30	4	
	Extra	60x40	1053 4062	3069464	60x40	30	9	
		60x60	1053 6062	3069466	60x60	30	4	
		60x90	1053 6092	3049706	60x90	30	4	
	Twincó	180x90	4136	3069469	180x90 (83x53,5 - pad)	20	4	
Washable Underpad	Extra	85x90	2580	3071631	90x175	1	15	Viecura
Bariatrics	Slips		10511300	3070387	105x83,5	8	32	Nateen

Device Product Description
Absorin® Comfort, Classic and Underpads
Revision 06/20.11.2025



	Pants		10511301	3070388	120x120	9	36	
--	-------	--	----------	---------	---------	---	----	--

Absorin® Classic							
Product		REF	SAP Article number	Size	Inner box pcs	Boxes/outer carton (pcs)	Supplier
Inlay	Mini - 35x12 cm	7045	3026984	36x11	50	4	Ontex
	Maxi - 60x15 cm	7050	3026987	60x15	28	4	

6.2.1 Product Classification

The Absorin® Comfort, Classic and Underpads are medical devices classified:

Classification under MDR: According to Annex VIII of the Medical Device Regulation (EU) 2017/745, Rule 1.

Rationale

Medical Device Regulation (EU) 2017/745 (MDR) Annex VIII, Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) (UK MDR 2002), Annex IX.

Duration of use Short term

Type of device Non-invasive Device

Classification

The following rule is applicable to this non-invasive devices:

Rule 1: Yes

Rule 2: Not applicable

Rule 3: Not applicable

Rule 4: Not applicable

4.2. Rule 2

Rule 2 does not apply as the device is not intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body.

4.3. Rule 3

Rule 3 does not apply as the device is not intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body.

4.4. Rule 4

Rule 4 does not apply as the device does not come into contact with injured skin or mucous membrane.

Conclusion: Absorin® Comfort, Classic and Underpads products are classified as class I medical devices.

Classification under UK MDR 2002: According to Annex IX, Rule 1 of Medical Devices Regulations 2002 (SI 2002 No 618, as amended), i.e:

Rationale	
Medical Devices Regulations 2002 (SI 2002 No 618, as amended) Annex IX Classification :	
<u>Duration of use</u>	Short term
<u>Type of device</u>	Non-invasive Device
<u>Classification</u>	
The following rule is applicable to this non-invasive devices:	
Rule 1:	Yes
Rule 2:	Not applicable
Rule 3:	Not applicable
Rule 4:	Not applicable
1.2. Rule 2	
Rule 2 does not apply as the device is not intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body.	
1.3. Rule 3	
Rule 3 does not apply as the device is not intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body.	
1.4. Rule 4	
Rule 4 does not apply as the device does not come into contact with injured skin or mucous membrane.	
Conclusion:	
Absorin® Comfort, Classic and Underpads products are classified as class I medical devices.	

6.2.2 Packaging specifications

For packaging procedure, specifications of layers and configuration, packaging and shelf life validation and shipping stability, reference is made to section 6.2 and 11.6 of the technical file.

6.2.3 Sterilization

This device is a non-sterile device.

6.2.3 Storage conditions

Absorin® Comfort, Classic and Underpads should be stored with their bags closed at a dry place.

6.2.4 Shelf life

Absorin® Comfort, Classic and Underpads

Product	Supplier	Shelf-life
Finette (Mini Plus, Normal, Extra, Super, Maxi, Maxi night), Level 2, Mincy, Slip, Pants)	Ontex	5 years
Finette (Mini, Ultra Mini)	Ontex	3 years
Pants	Livedo	3 years

Device Product Description
Absorin® Comfort, Classic and Underpads
Revision 06/20.11.2025



T-Fit	S.I.Cell	5 years
Sanette (distributed in Switzerland as Absorin® Comfort)	A.M.D.	5 years
Underpads	Greencare	3 years
Washable underpad	Viecura	5 years
Bariatrics	Nateen	3 years

6.2.5 Requirements for installation and servicing

This is not an active medical device and does not require any installation or servicing, no installation specification and no procedure for servicing is available, therefore this section is considered not applicable.

- END OF DOCUMENT -