Bastos Viegas

4560-164 Guilhufe, Penafiel - Portugal

Product Specification

Ref: 109 765

Alias: 777632001

Brand: flawa SOLVALINE® N

DRQ 14/21 REV.03 2026/06/18

Description:	Wundkompresse, verklebungsarm

STERILE EO

isento Latex free

isento PVC free

Final dimensions:	5 cm x5 cm x 1 plies
Composition:	Polyester,Polyethylene,Viscose.
Construction:	Double face/Face dupla
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	white
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g:	N.A.
Sterility Assur. Level_SAL:	≤10^-6
Fluorescence:	Absent
Weigth/sqm:	240±10% g/m2
Absorption cap. EN13726:	≥18 g/100 cm2
Absorption EN 1644-2:	≥10 g/g
Absorption Capacity:	≥1100 %
Thickness:	2,0 - 3,0 mm
MVTR:	>8600 g/m2/24h/37ºC
Water soluble substances:	≤0,7 %
Ether soluble substances:	≤0,5 %

Nr and Revision Date:	47 -- 2026/04/24
CE Class:	IEE
CE mark:	CE1639
Compliance with:	Reg MD/DM (EU) 2017/745
Applicable standards:	BP Perforated Film Abs Dre-British Pharmacopoeia Omitted Monograph Perforated Film Absorbent Dressing (partial compliance: compliance with Definition “dressing of low adherence consisting of three layers”, type I with a perforated wound facing layer, absorbent middle layer and backing layer, and type II in which the wound facing layer is similar to type I, absorbent middle layer and backing layer is identical with the wound facing layer (however with a GAP on the composition of fibres) and compliance of performance testing Absorbent capacity after compressing, Weight per unit area and Fluorescence) ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN ISO 13485:2016 A11:2021 ; EN ISO 11737-2:2020 ; EN 556-1:2024 ; EN ISO 11135:2014 ; EN ISO 11135:14 A1:2019- Not applicable ; EN 1422:2014 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:2020 ; EN ISO 10993-18:20 AMD1:23 ; EN ISO 10993-7:08:AC:2009 ; ISO 10993-7:2008 Amd1 2019 ; EN ISO 11607-1:2020 ; EN ISO 11607-1:20 A1:23 ; EN ISO 11607-2:2020 ; EN ISO 11607-2:20 A1:2023 ; CEN ISO TS 16775 2021 ; EN 17141:2020 ; EN ISO 14644-1:2015 ; EN ISO 14644-2:2015 ; EN ISO 14644-3:2019 ; EN ISO 14644-5:2025 ; ISO 2759:2014 ; ISO 3037:2022 ; ISTA Standard 2A ; ASTM F1980-21 ; ASTM F1929-23 ; ASTM F88/F88M-23 ; ASTM F1886/F1886M-25 ; ISO 2859 1:2026 ; ISO 8601-1:2019 ; ISO 8601-1:2019 AMD1:2022 ; IEC 62366-1:2015 A1:2020 ; IEC TR 62366-2:2016 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; ISO TR 24971:2020 ; EN ISO 15223-1:2021 ; EN ISO 15223-1:21 AMD2025 ; EN ISO 20417:2026 ; ISO TR 20416:2020 ;
GMDN:	46854 - Wound-nonadherent□dressing, absorbent, non-antimicrobial
EMDN:	M040204 - NON-ADHERENT ABSORBENT DRESSINGS

PACKING

Level	Units	Type	Dimension	Stamp	Labels
1	1	Flexible peel-open pack	80x100mm		
2	20	Folding box	074x083x103mm ref.1097		labeled

20 PAP 3	2700	Carton box	786x386x321mm	stamped	labeled

Basic UDI	56056221115002JD
	EAN 1th level/nivel:05605622247793
	EAN 2th level/nivel:15605622447794
	EAN Carton Box/Caixa:25605622047793

Important Notes:	The device is intended to be used on a single patient during one single procedure to prevent risks from contamination, including possible infections, and/or functional damage.

Storage instructions:	Store in a dry place at room temperature and protect from sunlight. The product has a good stability and therefore, normal conditions of medical devices storage shall apply.
Waste instructions:	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Intended purpose:	As a primary dressing for the treatment of light to moderate exuding wounds, such as minor injuries (cuts and abrasions), post-surgical wounds and small partial thickness burns. As a secondary dressing to enhance absorption capacity. Round design may be preferred to use during breastfeeding for absorption or to cover and protect nipples.

Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsibility.

Environment - Packaging waste	Weight(gr) of packing material used in 100 pcs	257	

ISSUED BY: Quality Management Department, 2026/08/31

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