

DECLARATION OF CONFORMITY

Document Number: DOC-03627 **Version:** 1.0

Title: Dansac UK DOC Nova 1 - One-Piece Closed Ostomy Pouch

Signatures:

Signed By : Hansen, Johnny (hansenj1)

Decision : Approved

Decision Date : 22 Sep 2022 06:38:29 (GMT-05:00)

Role : QMS Site Quality Mgmt

Purpose : opdatere overskrift

Meaning Of Signature : Based on the intent of my role on this workflow, by signing this record I attest that I have reviewed it for completeness and agree with its content.

Signed By : Middaugh, Megan (middauma)

Decision : Approved

Decision Date : 22 Sep 2022 08:47:11 (GMT-05:00)

Role : QMS Tactical Mgmt

Purpose : opdatere overskrift

Meaning Of Signature : Based on the intent of my role on this workflow, by signing this document I attest that I have reviewed it, and evaluated its content in order to endorse it for use.

Signed By : Linde, Charlotte E. (cel)

Decision : Approved

Decision Date : 23 Sep 2022 02:10:29 (GMT-05:00)

Role : FR Regulatory


Purpose : opdatere overskrift

Meaning Of Signature : Jeg bekræfter, at jeg har gennemgået dette dokument og evalueret at indholdet stemmer overens med gældende praksis. I attest that I have reviewed this document and evaluated its content in order to endorse it for use.

Number (version)	DOC-03627 (0.2)
Title	Dansac UK DOC Nova 1 - One-Piece Closed Ostomy Pouch
Hierarchy	Level VI - Quality Record
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UK Declaration of Conformity

	DANSAC A/S Lille Kongevej 304 DK – 3480 Fredensborg	
UK Responsible Person & Importer	Hollister Ltd Building 1010 Winnersh Triangle Business Park Eskdale Road Winnersh Berks RG41 5TS	

Dansac A/S uses the following procedures for the UKCA-labelling of their products according the Medical Devices Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478). Class I UK conformity declaration according to UK MDR 2002 Rule 13 / MDD Annex VI

Classification	(UK MDR 2002 Regulation 7 / MDD Annex IX): Class I (Rule 4)
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Intended Use	This product is intended to collect output from a stoma (e.g., colostomy, ileostomy) or skin opening (e.g., wound, fistula).
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This declaration of conformity is issued under the sole responsibility of Dansac A/S. We hereby declare that the medical device(s) specified above meet the provision of the UK Regulation MDR 2002 for medical devices. This declaration is supported by the Quality System approval to BS EN ISO 13485:2016+A11:2021 issued by NSAI.
All supporting documentation is retained at the premises of the manufacturer.

Signed by: Quality Assurance Manager DK – 3480 Fredensborg	Decision Date: Date
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Title	Dansac UK DOC Nova 1 - One-Piece Closed Ostomy Pouch
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REF	Nova 1	1-Piece Closed Ostomy Pouch, GX	en
801-20, 802-20, 806-20, 829-20,			
GMDN	31066		
Basic UDI	5709817D02P037S00955X		

REF	Nova 1	1-Piece Closed Ostomy Pouch, GX, Convex	en
831-24, 832-37			
GMDN	31066		
Basic UDI	5709817D02P037S00965Z		

REF	Nova 1	1-Piece Closed Ostomy Pouch, GX, Soft Convex	en
871-30, 871-35			
GMDN	31066		
Basic UDI	5709817D02P037S009763		