DECLARATION OF CONFORMITY

Document Number: DOC-03593 **Version:** 2.0
Title: Hollister UK DOC Conform 2 - Two-Piece Ostomy Skin Barrier

Signatures:

Signed By : Lichtenwalner, Ben (lichtebd)
Decision : Approved
Decision Date : 02 Nov 2022 13:23:05 (GMT-05:00)
Role : QMS Tactical Mgmt
Purpose : Update UK Declaration of Conformities
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 : 04 Nov 2022 09:26:38 (GMT-05:00)
Role : Regulatory Affairs Approver
Purpose : Update UK Declaration of Conformities
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.

Number (version)	DOC-03593 (2.0)
Title	Hollister UK DOC Conform 2 - Two-Piece Ostomy Skin Barrier
Hierarchy	Level VI - Quality Record

Hollister

UK Declaration of Conformity

	Hollister Incorporated 2000 Hollister Drive Libertyville, IL, USA	
UK Responsible Person & Importer	Hollister Ltd Building 1010 Winnersh Triangle Business Park Eskdale Road Winnersh Berks RG41 5TS	

Hollister Incorporated 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)

Intended Use	This product is part of a two-piece ostomy pouching system intended to collect output from a stoma (e.g., colostomy, ileostomy, or urostomy) or skin opening (e.g., wound, fistula).

This declaration of conformity is issued under the sole responsibility of Hollister Incorporated. We hereby declare that the medical device(s) specified above meet the provision of the UK MDR 2002 for medical devices. This declaration is supported by the Quality System approval to EN ISO 13485:2016+A11:2021 issued by NSAI.
All supporting documentation is retained at the premises of the manufacturer.

Signed by:	**Decision Date:**
Regulatory Affairs Manager (en) Libertyville, IL, USA	Date

REF	Conform 2	2-Piece Ostomy Skin Barrier, Softflex
23200, 24200, 25200, 27200		
GMDN	48159	
Basic UDI	610075D01P064S0079AD	

REF	Conform 2	2-Piece Ostomy Skin Barrier, FlexWear
33500, 33200, 34200, 34225, 34500, 34520, 34525, 34530, 35200, 35500, 35535, 35540, 37500, 38500		
GMDN	48159	
Basic UDI	610075D01P064S00819Y	

REF	Conform 2	2-Piece Ostomy Skin Barrier, FlexWear, Convex
24300, 24320, 24322, 24325, 25300, 25329, 25332, 25335, 27300, 34600, 34620, 34622, 34625, 35600, 35629, 35632, 37600		
GMDN	48158	
Basic UDI	610075D01P064S0082A2	

REF	Conform 2	2-Piece Ostomy Skin Barrier, CeraPlus
14200, 14500, 15200, 15500, 17200, 17500,		
GMDN	48159	
Basic UDI	610075D01P064S0085A8	

REF	Conform 2	2-Piece Ostomy Skin Barrier, CeraPlus, Convex
14100, 14600, 14620, 14625, 15100, 15600, 15629, 15632, 17100, 17600		
GMDN	48158	
Basic UDI	610075D01P064S0086AA	

REF	Conform 2	2-Piece Ostomy Skin Barrier, CeraPlus, Soft Convex
14A20, 15A29		
GMDN	48158	
Basic UDI	610075D01P064S0087AC	