

DECLARATION OF CONFORMITY

Document Number: DOC-07690 **Version:** 1.0

Title: Hollister MDR DOC 1-Piece Ostomy Pouches

Signatures:

Signed By : Green, Peter (greenpc)

Decision : Approved

Decision Date : 16 May 2025 13:52:58 (GMT-05:00)

Role : QMS Subject Matter Expert

Purpose : Approve new Hollister EU MDR DOC for One Piece Ostomy Pouches

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 : Lichtenwalner, Ben (lichtebd)

Decision : Approved

Decision Date : 02 Jun 2025 11:50:08 (GMT-05:00)

Role : QMS Tactical Mgmt

Purpose : Approve new Hollister EU MDR DOC for One Piece Ostomy Pouches

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-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	



	Hollister Incorporated 2000 Hollister Drive Libertyville, IL, USA	SRN #: US-MF-000027818
	Hollister ULC Foxford Road, Ballina Co. Mayo, F26 F3X5 Ireland	SRN #: IE-AR-000022119

EU Declaration of Conformity (en)

	ISO 639	ISO 3166-1
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 Regulation (EU) MDR 2017/745 for medical devices.	en	IE, ML, GB

Classification	(Annex VIII): Class I (Rule 4)
Conformity Assessment Procedure	Class I: Not Applicable

GMDN	Intended Use
31075	<u>1-Piece Drainable Ostomy Pouch</u> : This product is intended to collect output from a stoma (e.g., colostomy, ileostomy) or skin opening (e.g., wound, fistula).
31066	<u>1-Piece Closed Ostomy Pouch</u> : This product is intended to collect output from a stoma (e.g., colostomy, ileostomy) or skin opening (e.g., wound, fistula).
64583	<u>1-Piece Urostomy Pouch</u> : This product is intended to collect output from a stoma (e.g., urostomy) or skin opening (e.g., wound, fistula).

Signed by: Regulatory Affairs Manager Libertyville, IL, USA	Decision Date:
---	-----------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

Moderma Flex		GMDN 31075
Basic UDI	EMDN	REF
610075D01P040S00026L	A1001010102	26200, 26500, 26900, 26901, 26920, 26925, 26930, 26935, 28100, 28120, 28125, 28130, 28135, 28200, 28220, 28225, 28230, 28235, 28240, 28300, 28301, 28320, 28325, 28330, 28335, 28340, 28400, 28401, 28500, 2824055, 2834001, 2834055
610075D01P040S00016J	A1001010202	26800, 26801, 26820, 26825, 26830, 2683038, 2683051, 2683120, 2683125, 2683130, 2683135, 26835, 26900, 26901, 26920, 26925, 26930, 26935
610075D01P040S00066U	A1001010102	5625064, 5834064, 58300, 58320, 58325, 58335, 58400, 58420, 58425, 58330, 58340, 58430, 58435, 58440
610075D01P040S00056S	A1001010202	56600, 56601, 56602, 56620, 56625, 56630, 56700, 56701, 56702, 56725, 56800, 56801, 56802, 56820, 56825, 56830, 5683025, 5683038, 5683051, 5683120, 5683125, 5683130, 5683135, 5683140, 5683145, 56835, 56840, 56845, 56900, 56901, 56902, 56920, 56930, 56935, 56940, 56945, 56640
610075D01P040S00086Y	A1001010202	5681025, 5681038, 5681055, 5681120, 5681125, 5681130, 5681135, 5681140, 5691025, 5691038, 5691055, 5691120, 5691125, 5691130, 5691135, 5691140
610075D01P040S00046Q	A1001010102	53400, 53425, 53430, 53435, 53500, 53525, 53530, 53535, 54200, 54225, 54230, 54235, 54300, 54325, 54330, 54335, 63400, 63500, 64200, 64225, 64230, 64235, 64300, 64325, 64330, 64335, 542200, 543200, 534200
610075D01P040S004678	A1001010202	53700, 53701, 53702, 53730, 53735, 53900, 53901, 53902, 53930, 53935, 54600, 54601, 54602, 54625, 54630, 54635, 54800, 54801, 54802, 54825, 54830, 54835, 63700, 63701, 63702, 63900, 63901, 63902, 63930, 63935, 64600, 64601, 64602, 64625, 64630, 64635, 64800, 64801, 64802, 64825, 64830, 64835, 546200, 548200, 546201, 548201
610075D01P040S00036N	A1001010202	53000, 53001, 53002, 53100, 53101, 53102, 54000, 54001, 54002, 54025, 54030, 54035, 54100, 54101, 54102, 54125, 54130, 54135, 63000, 63001, 63002, 63030, 63100, 63101, 63102, 63125, 63130, 63135, 64000, 64001, 64002, 64025, 64030, 64035, 64100, 64101, 64102, 64125, 64130, 64135, 63025, 540200, 540201, 530200, 541200, 541201, 531200, 531201, 541225, 541229, 541232, 541238, 530201, 540225, 540229, 540232, 541235

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

610075D01P023S00297D	A1001010202	20070, 20110
----------------------	-------------	--------------

Hollister		GMDN 31075
Basic UDI	EMDN	REF
610075D01P023S00306W	A1001020102	26064, 26364
610075D01P023S00316Y	A1001020202	83025, 83038, 83055, 83125, 83130, 83135

Pouchkins		GMDN 31075
Basic UDI	EMDN	REF
610075D01P040S01777Q	A1001010102	3795, 3796

Karaya 5		GMDN 31075
Basic UDI	EMDN	REF
610075D01P040S02126Z	A1001010102	3112, 3113, 3114, 3115, 3118, 3119, 3133, 3138, 3139, 3222, 3223, 3224, 3225, 3228, 3229, 3273, 3274, 3275, 3276, 3278, 3279, 3603, 3604, 3605, 3606, 3608, 3609, 3663, 3664, 3668, 3669

Suavita		GMDN 31075
Basic UDI	EMDN	REF
610075D01P040S004474	A1001010102	7610, 7620, 7630, 7640

Compact		GMDN 31075
Basic UDI	EMDN	REF
610075D01P040S03587W	A1001010102	3251
610075D01P040S03597Y	A1001010202	3285

Compact / Impression C		GMDN 31075
Basic UDI	EMDN	REF
610075D01P040S00106K	A1001010202	3260, 3261, 3262, 3263, 3264
610075D01P040S00116M	A1001010202	3613, 3614

Moderma Flex		GMDN 31066
Basic UDI	EMDN	REF
610075D01P038S00429P	A1001010202	2261025, 2261038, 2261055, 2261120, 2261125, 2261130, 2261135, 2261140, 2281025, 2281038, 2281055, 2281120, 2281125, 2281130, 2281135, 2281140, 2281025, 2281038, 2281055
610075D01P038S00419M	A1001010202	22800, 22801, 22820, 22825, 22830, 22835, 22900, 22901, 22920, 22925, 22930, 22935, 42800, 42801, 42820, 42825, 42830, 42835, 2283038, 2283051, 2283120, 2283125, 2283130, 2283135

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

610075D01P038S00409K	A1001010102	22100, 22120, 22125, 22130, 22135, 22140, 22145, 22300, 22301, 22325, 22330, 22335, 22401, 22425, 22430, 22435, 22440, 22500, 42100, 42120, 42125, 42130, 42135, 42140, 42145, 42300, 42301, 42325, 42330, 42335, 2214055, 2234001, 2234055; 22400
610075D01P038S0244A5	A1001010202	52200, 522100, 522101, 52201, 522125, 522130, 522135, 522140
610075D01P038S00439R	A1001010102	52100, 52125, 52130, 52135, 62100, 62125, 62130, 62135, 521101
610075D01P038S00449T	A1001010202	52600, 52601, 52625, 52630, 52635, 62600, 62601, 62625, 62630, 62635, 526100, 526101

Hollister		GMDN 31066
Basic UDI	EMDN	REF
610075D01P038S00379W	A1001010102	1792, 1794, 1796, 3184, 3186

Pouchkins		GMDN 31066
Basic UDI	EMDN	REF
610075D01P038S0185AE	A1001010102	3777

Karaya 5		GMDN 31066
Basic UDI	EMDN	REF
610075D01P038S02119N	A1001010102	2163, 2164, 2165, 2169, 3323, 3324, 3325, 3326, 3328, 3329, 3553, 3554, 3558, 7163, 7164, 7165, 7166, 7168, 7169

Compact / Impression C / Nuance / FirstChoice		GMDN 31066
Basic UDI	EMDN	REF
610075D01P038S00389Y	A1001010102	3192, 3193, 3194, 3460, 3470, 3472, 3473, 3474, 3475, 3478, 3479, 3520, 3523, 3524, 3525, 3528, 3529
610075D01P038S0039A	A1001010202	3493, 3491, 3492, 3494, 3495, 3496, 3497, 3498, 3499, 3591, 3592, 3593, 3594, 3596

Moderma Flex		GMDN 64583
Basic UDI	EMDN	REF
610075D01P044S00478W	A1001030102	29100, 29120, 29125, 29130, 29135, 29500, 2919055, 2919120, 2919125, 2919130, 2919135, 2959055
610075D01P044S00488Y	A1001030202	29200, 29201, 29220, 29220, 29225, 29230, 29235, 29300, 29301, 29320, 29325, 29330, 29335, 2929025, 2929038, 2929120, 2929125, 2929130, 2929135, 2939025, 2939038, 2939120, 2939125, 2939130, 2939135
610075D01P044S004992	A1001030202	2993025, 2993038, 2993055, 2993120, 2993125,

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

		2993130
610075D01P044S00508K	A1001030102	29000, 29025, 29030, 29035, 29040, 29400, 29420, 29425, 29430, 29435, 29440, 2909064, 2909120, 2909125, 2909130, 2909135, 2909140, 2949064, 2949120, 2949125, 2949130, 2949135, 2949140
610075D01P044S00518M	A1001030202	29600, 29601, 29620, 29625, 29630, 29635, 29640, 29700, 29701, 29720, 29725, 29730, 29735, 29740, 2969025, 2969038, 2969120, 2969125, 2969130, 2969135, 2969140, 2979025, 2979038, 2979120, 2979125, 2979130, 2979135, 2979140
610075D01P044S00528P	A1001030102	59400
610075D01P044S00538R	A1001030202	59620, 59625, 59630, 59700, 59701, 59702, 596200, 597200, 596201, 597201, 59720, 59725, 59730, 59735
610075D01P044S00548T	A1001030202	59820, 59825, 59830, 59900, 59901, 59902, 598201, 599201, 598200, 599200, 599220, 599225, 599230, 59920, 59925, 59930

Pouchkins		GMDN 64583
Basic UDI	EMDN	REF
610075D01P044S016799	A1001030102	3778, 3797

Karaya 5		GMDN 64583
Basic UDI	EMDN	REF
610075D01P044S00578Z	A1001030102	1432, 1433, 1434, 1438

Compact / Impression C / Nuance / FirstChoice		GMDN 64583
Basic UDI	EMDN	REF
610075D01P044S00558V	A1001030202	1401, 1442, 1443, 1447, 1448
610075D01P044S00568X	A1001030202	1439, 1450, 1451, 1452, 1453, 1454, 1455, 1456, 1457, 1458, 1459, 1460, 1481, 1482, 1483, 1484, 1485, 1486, 1487, 1488, 1489

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

EU-overensstemmelseserklæring (da)

	ISO 639	ISO 3166-1
Hollister Incorporated har eneansvaret for denne overensstemmelseserklæring. Vi erklærer hermed, at det ovenfor beskrevne medicinske udstyr opfylder bestemmelserne i forordningen (EU) 2017/745 om medicinsk udstyr.	da	DK

Klassificering	(Bilag VIII): klasse I (regel 4)
Overensstemmelsesvurderingsprocedure	Klasse I: Ikke relevant

GMDN	Tilsigtet brug
31075	<u>Tømbar 1-dels stomipose</u> : Dette produkt er beregnet til opsamling af output fra en stomi (f.eks. kolostomi, ileostomi) eller hudåbning (f.eks. sår eller fistel).
31066	<u>Lukket 1-dels stomipose</u> : Dette produkt er beregnet til opsamling af output fra en stomi (f.eks. kolostomi, ileostomi) eller hudåbning (f.eks. sår eller fistel).
64583	<u>1-dels urostomipose</u> : Dette produkt er beregnet til opsamling af output fra en stomi (f.eks. urostomi) eller hudåbning (f.eks. sår eller fistel).

Underskrevet af: Regulatory Affairs Manager Libertyville, IL, USA	Dato for afgørelsen:
---	-----------------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

EU-conformiteitsverklaring (nl)

	ISO 639	ISO 3166-1
Deze conformiteitsverklaring wordt uitgegeven onder de exclusieve verantwoordelijkheid van Hollister Incorporated. Hierbij verklaren wij dat de hierboven genoemde medische hulpmiddelen voldoen aan de vereisten van de verordening (EU) MDR 2017/745 voor medische hulpmiddelen.	nl	BE, NL

Classificatie	(Bijlage VIII): klasse I (regel 4)
Conformiteitsbeoordelingsprocedure	Klasse I: Niet van toepassing

GMDN	Beoogd gebruik
31075	<u>Eindelijk open stomaopvangzakje</u> : Dit product is bedoeld om uitscheiding van een stoma (bijv. colostoma of ileostoma) of een huidopening (bijv. wond of fistel) op te vangen.
31066	<u>Eindelijk gesloten stomaopvangzakje</u> : Dit product is bedoeld om uitscheiding van een stoma (bijv. colostoma of ileostoma) of een huidopening (bijv. wond of fistel) op te vangen.
64583	<u>Eindelijk uro-opvangzakje</u> : Dit product is bedoeld om uitscheiding van een stoma (bijv. urostoma) of een huidopening (bijv. wond of fistel) op te vangen.

Gesigneerd door: Manager reglementaire zaken Libertyville, IL, USA	Datum van de beslissing:
--	-------------------------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

EU-vaatimustenmukaisuusvakuutus (fi)

	ISO 639	ISO 3166-1
Tämä vaatimustenmukaisuusvakuutus on annettu Hollister Incorporatedin yksinomaisella vastuulla. Täten vakuutamme, että edellä mainitut lääkinälliset laitteet ovat lääkinällisiä laitteita koskevan asetuksen (EU) 2017/745 säännösten mukaisia.	fi	FI

Luokitus	(Liite VIII): luokka I (sääntö 4)
Vaatimustenmukaisuuden arviointimenettely	Luokka I: ei sovelleta

GMDN	Käyttötarkoitus
31075	<u>1-osainen tyhjennettävä avannepussi</u> : Tämä tuote on tarkoitettu keräämään avanteen (esim. paksu-tai ohutsuoliavanne) tai ihon aukkojen (esim. haava, fisteli) eritteitä
31066	<u>1-osainen suljettu avannepussi</u> : Tämä tuote on tarkoitettu keräämään avanteen (esim. paksu-tai ohutsuoliavanne) tai ihon aukkojen (esim. haava, fisteli) eritteitä
64583	<u>1-osainen virtsa-avannepussi</u> : Tämä tuote on tarkoitettu keräämään avanteen (esim. virtsa-avanne) tai ihon aukkojen (esim. haava, fisteli) eritteitä

Allekirjoittanut: Sääntelyasiohtaja Libertyville, IL, USA	Päätöksen päivämäärä:
---	------------------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

Déclaration UE de conformité (fr)

	ISO 639	ISO 3166-1
Cette déclaration de conformité est délivrée sous la seule responsabilité de Hollister Incorporated. Nous déclarons par la présente que le ou les dispositifs médicaux spécifiés ci-dessus satisfont aux dispositions du Règlement (UE) 2017/745 relatif aux dispositifs médicaux.	fr	BE, FR, CH

Classification	(Annexe VIII): Classe I (règle 4)
Procédure d'évaluation de la conformité	Classe I: sans objet

GMDN	Utilisation prévue
31075	<u>Poche vidable 1 pièce pour stomathérapie</u> : Ce produit est destiné à recueillir les substances éliminées par une stomie (p. ex., colostomie,iléostomie) ou par une ouverture cutanée (p. ex., plaie, fistule)
31066	<u>Poche fermée 1 pièce pour stomathérapie</u> : Ce produit est destiné à recueillir les substances éliminées par une stomie (p. ex., colostomie,iléostomie) ou par une ouverture cutanée (p. ex., plaie, fistule)
64583	<u>Poche pour urostomie 1pièce</u> : Ce produit est destiné à recueillir les substances éliminées par une stomie (p. ex., urostomie) ou par une ouverture cutanée (p. ex., plaie, fistule)

Signé par: Responsable des affaires réglementaires Libertyville, IL, USA	Date de la décision :
--	------------------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

EU-Konformitätserklärung (de)

	ISO 639	ISO 3166-1
Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt Hollister Incorporated. Hiermit erklären wir, dass das oben genannte Medizinprodukt bzw. die oben genannten Medizinprodukte der Verordnung (EU) 2017/745 über Medizinprodukte entsprechen.	de	AT, BE, DE, CH

Klassifizierung	(Anhang VIII): Klasse I (Regel 4)
Konformitätsbewertungsverfahren	Klasse I: Nicht zutreffend

GMDN	Verwendungszweck
31075	<u>Einteiliger Stoma-Ausstreifbeutel</u> : Dieses Produkt dient zum Auffangen der Ausscheidungen eines Stomas (z. B. Kolostoma oder Ileostoma) oder einer Hautöffnung (z. B. Wunde oder Fistel).
31066	<u>Einteiliger geschlossener Stomabeutel</u> : Dieses Produkt dient zum Auffangen der Ausscheidungen eines Stomas (z. B. Kolostoma oder Ileostoma) oder einer Hautöffnung (z. B. Wunde oder Fistel).
64583	<u>Einteiliger Urostomiebeutel</u> : Dieses Produkt dient zum Auffangen der Ausscheidungen eines Stomas (z. B. Urostoma) oder einer Hautöffnung (z. B. Wunde oder Fistel).

Unterzeichnet von: Regulatory Affairs Manager Libertyville, IL, USA	Datum der Entscheidung:
---	------------------------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

Δήλωση συμμόρφωσης με την ΕΕ (el)

	ISO 639	ISO 3166-1
Αυτή η δήλωση συμμόρφωσης εκδίδεται υπό την αποκλειστική ευθύνη της Hollister Incorporated. Με το παρόν δηλώνουμε ότι τα ιατροτεχνολογικά προϊόντα που καθορίζονται ανωτέρω πληρούν τις διατάξεις του Κανονισμού (ΕΕ) MDR 2017/745 για τα ιατροτεχνολογικά προϊόντα.	el	CY, GR

Ταξινόμηση	(Παράρτημα VIII): Τάξης I (Κανόνας 4)
Διαδικασία αξιολόγησης συμμόρφωσης	Κατηγορία I: Δεν ισχύει

GMDN	Προβλεπόμενη χρήση
31075	<u>Αποστραγγιζόμενος σάκος στομίας 1 τεμαχίου</u> : Αυτό το προϊόν προορίζεται για τη συλλογή της παραγόμενης ύλης από μια στομία (π.χ. κολοστομία, ειλεοστομία) ή ένα άνοιγμα στο δέρμα (π.χ. τραύμα, συρίγγιο).
31066	<u>Κλειστός σάκος στομίας 1 τεμαχίου</u> : Αυτό το προϊόν προορίζεται για τη συλλογή της παραγόμενης ύλης από μια στομία (π.χ. κολοστομία, ειλεοστομία) ή ένα άνοιγμα στο δέρμα (π.χ. τραύμα, συρίγγιο).
64583	<u>Σάκος ουροστομίας 1 τεμαχίου</u> : Αυτό το προϊόν προορίζεται για τη συλλογή της παραγόμενης ύλης από μια στομία (π.χ. ουροστομία) ή ένα άνοιγμα στο δέρμα (π.χ. τραύμα, συρίγγιο).

Υπογραφή: Διευθυντής κανονιστικών υποθέσεων Libertyville, IL, USA	Ημερομηνία απόφασης:
---	---------------------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

Declaración de conformidad de la UE (es)

	ISO 639	ISO 3166-1
Esta declaración de conformidad se emite bajo la exclusiva responsabilidad de Hollister Incorporated. Por la presente declaramos que el/los dispositivo(s) médico(s) especificado(s) anteriormente cumple(n) con la disposición del Reglamento (UE) MDR 2017/745 para dispositivos médicos.	es	ES

Clasificación	(Anexo VIII): Clase I (Norma 4)
Procedimiento de evaluación de la conformidad	Clase I: No aplicable

GMDN	Uso previsto
31075	<u>Bolsa de ostomía abierta de 1 pieza</u> : Este producto recoge el contenido de un estoma (p. ej., una colostomía o ileostomía) o una abertura cutánea (p. ej., una herida o fistula)
31066	<u>Bolsa de ostomía cerrada de 1 pieza</u> : Este producto recoge el contenido de un estoma (p. ej., una colostomía o ileostomía) o una abertura cutánea (p. ej., una herida o fistula)
64583	<u>Bolsa de urostomía de 1pieza</u> : Este producto recoge el contenido de un estoma (p. ej., una urostomía) o una abertura cutánea (p. ej., una herida o fistula).

Firmado por: Director de asuntos reglamentarios Libertyville, IL, USA	Fecha de decisión:
---	---------------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

Dichiarazione di conformità UE (it)

	ISO 639	ISO 3166-1
La presente dichiarazione di conformità è rilasciata sotto l'esclusiva responsabilità di Hollister Incorporated. Con la presente si dichiara che i dispositivi medici sopra specificati soddisfano le disposizioni del Regolamento (UE) MDR 2017/745 relativo ai dispositivi medici.	it	IT, CH

Classificazione	(Allegato VIII): Classe I (Regola 4)
Procedura di valutazione della conformità	Classe I: Non applicabile

GMDN	Utilizzo previsto
31075	<u>Sacca per ileostomia monopezzo</u> : Il prodotto è destinato a raccogliere le fuoriuscite da uno stoma (come nei casi di colostomia o ileostomia) o da aperture presenti sulla cute (ad es. ferite, fistole).
31066	<u>Sacca per colostomia monopezzo</u> : Il prodotto è destinato a raccogliere le fuoriuscite da uno stoma (come nei casi di colostomia o ileostomia) o da aperture presenti sulla cute (ad es. ferite, fistole).
64583	<u>Sacca per urostomia monopezzo</u> : Il prodotto è destinato a raccogliere le fuoriuscite da uno stoma (come nel caso di urostomia) o da aperture presenti sulla cute (ad es., ferite, fistole).

Firmato da: Regulatory Affairs Manager Libertyville, IL, USA	Data della decisione:
--	------------------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

EU-samsvarserklæring (no)

	ISO 639	ISO 3166-1
Hollister incorporated er ene og alene ansvarlig for utstedelsen av denne samsvarserklæringen. Vi erklærer herved at de medisinske enhetene spesifisert ovenfor oppfyller kravene i reguleringen (EU) MDR 2017/745 for medisinsk utstyr.	no	NO

Klassifisering	(Tillegg VIII): klasse I (regel 4)
Prosedyre for samsvarsvurdering	Klasse I: Ikke aktuelt

GMDN	Tiltenkt bruk
31075	<u>Endels tømbar stomipose</u> : Stomiprodukter er tenkt brukt for å bistå ved kolostomi-, ileostomi- eller urostomiavledning og er utviklet for å avlede urin eller avføring gjennom en kirurgisk opprettet, kunstig åpning eller stoma
31066	<u>Endels lukket stomipose</u> : Stomiprodukter er tenkt brukt for å bistå ved kolostomi-, ileostomi- eller urostomiavledning og er utviklet for å avlede urin eller avføring gjennom en kirurgisk opprettet, kunstig åpning eller stoma
64583	<u>Endels urostomipose</u> : Dette produktet er beregnet på å samle avfall fra en stomi (f.eks. urostomi) eller åpning i huden (f.eks. sår, fistel).

Signert av: Regulatory Affairs Manager Libertyville, IL, USA	Dato for avgjørelse:
--	-----------------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

Declaração de conformidade da UE (pt)

	ISO 639	ISO 3166-1
Esta declaração de conformidade é emitida sob a exclusiva responsabilidade da Hollister Incorporated. Declaramos, pelo presente documento, que os dispositivos médicos acima especificados cumprem as disposições do Regulamento (UE) 2017/745 relativo aos dispositivos médicos.	pt	PT

Classificação	(Anexo VIII): classe I (regra 4)
Procedimento de avaliação da conformidade	Classe I: Não aplicável

GMDN	Utilização prevista
31075	<u>1 Peças - Saco de ostomia drenável</u> : Este produto destina-se a recolher os efluentes de um estoma (por ex., colostomia, ileostomia) ou de uma lesão cutânea (por ex., ferida, fístula).
31066	<u>1 Peças - Saco de ostomia fechado</u> : Este produto destina-se a recolher os efluentes de um estoma (por ex., colostomia, ileostomia) ou de uma lesão cutânea (por ex., ferida, fístula).
64583	<u>1 Peças - Saco de urostomia</u> : Este produto destina-se a recolher os efluentes de um estoma (por ex., urostomia), ou de uma lesão cutânea (por ex., ferida, fístula).

Assinado por: Gestor de assuntos regulamentares Libertyville, IL, USA	Data da Decisão:
---	-------------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

Declarație de conformitate CE (ro)

	ISO 639	ISO 3166-1
Prezenta declarație de conformitate este emisă în baza responsabilității exclusive a Hollister Incorporated. Declarăm prin prezenta că dispozitivul(le) medical(e) indicat(e) mai sus îndeplinește/îndeplinesc prevederile Regulamentului (UE) privind dispozitivele medicale (MDR) 2017/745.	ro	RO

Clasificare	(Anexa VIII): Clasa I (Regula 4)
Procedură de evaluare a conformității	Clasa I: Nu se aplică

GMDN	Destinație
31075	<u>Pungă drenabilă monocomponentă pentru stoma</u> : Acest produs este destinat pentru colectarea produsului dintr-o stomă (de ex. colostomie, ileostomie) sau dintr-un orificiu cutanat (de ex. plagă, fistulă).
31066	<u>Pungă închisă monocomponentă pentru stoma</u> : Acest produs este destinat pentru colectarea produsului dintr-o stomă (de ex. colostomie, ileostomie) sau dintr-un orificiu cutanat (de ex. plagă, fistulă).
64583	<u>Pungă monocomponentă pentru urostomie</u> : Acest produs este destinat pentru colectarea produsului dintr-o stomă (de ex. urostomie) sau dintr-un orificiu cutanat (de ex. plagă, fistulă).

Semnat de: Director Afaceri de Reglementare Libertyville, IL, USA	Data deciziei:
---	-----------------------

Number (version)	DOC-07690 (0.2)
Title	Hollister MDR DOC 1-Piece Ostomy Pouches
Hierarchy	Level VI - Quality Record
©2025 Hollister Incorporated and Dansac A/S	

EU-försäkran om överensstämmelse (sv)

	ISO 639	ISO 3166-1
Denna försäkran om överensstämmelse utfärdas under eget ansvar av Hollister Incorporated. Vi försäkrar härmed att den eller de medicintekniska produkter som anges ovan uppfyller bestämmelserna i förordning (EU) MDR 2017/745 för medicintekniska produkter.	sv	FI, SE

Klassificering	(Bilaga VIII): Klass I (regel 4)
Förfarande för bedömning av överensstämmelse	Klass I: Ej tillämpligt

GMDN	Avsedd användning
31075	<u>1-dels tömbar stomipåse</u> : Denna produkt är avsedd att samla upp utflödet från en stomi (t.ex. kolostomi, ileostomi) eller hudöppning (t.ex. sår, fistel).
31066	<u>1-dels sluten stomipåse</u> : Denna produkt är avsedd att samla upp utflödet från en stomi (t.ex. kolostomi, ileostomi) eller hudöppning (t.ex. sår, fistel).
64583	<u>1-dels urostomipåse</u> : Denna produkt är avsedd att samla upp utflödet från en stomi (t.ex. urostomi) eller hudöppning (t.ex. sår, fistel).

Undertecknat av: Chef för registrerings- och regelfrågor Libertyville, IL, USA	Datum för beslut:
--	--------------------------