

## DECLARATION OF CONFORMITY

**Document Number:** DOC-07703      **Version:** 1.0

**Title:** Hollister MDR DOC Ostomy Systems for Spain

### **Signatures:**

Signed By : Green, Peter (greenpc)

Decision : Approved

Decision Date : 16 May 2025 15:38:50 (GMT-05:00)

Role : QMS Subject Matter Expert

Purpose : Approve new Hollister EU MDR DOC Ostomy Systems for Spain

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 11:39:48 (GMT-05:00)

Role : QMS Tactical Mgmt

Purpose : Approve new Hollister EU MDR DOC Ostomy Systems for Spain

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.

<b>Number (version)</b>	<b>DOC-07703 ( 0.2 )</b>
<b>Title</b>	Hollister MDR DOC Ostomy Systems for Spain
<b>Hierarchy</b>	Level VI - Quality Record
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	Hollister Incorporated 2000 Hollister Drive Libertyville, IL, USA	SRN #: US-MF-000027818
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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

<b>Classification</b>	(Annex VIII): Class I (Rule 1 and 4)
<b>Conformity Assessment Procedure</b>	Class I: Not Applicable

<b>GMDN</b>	<b>Intended Use</b>
<b>62525</b>	Ostomy Kits contain ostomy devices intended to collect output from a stoma (e.g., colostomy, ileostomy, urostomy) or skin opening (e.g., wound, fistula). Ostomy Kits can also contain ostomy accessories, cosmetics, and consumer products to help with product application and care of the stoma.
<b>62526</b>	Ostomy Kits contain ostomy devices intended to collect output from a stoma (e.g., colostomy, ileostomy, urostomy) or skin opening (e.g., wound, fistula). Ostomy Kits can also contain ostomy accessories, cosmetics, and consumer products to help with product application and care of the stoma.

Signed by: Regulatory Affairs Manager (en) Libertyville, IL, USA	<b>Decision Date:</b>
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<b>Conform 2</b>		<b>GMDN 62525</b>
<b>Basic UDI</b>	<b>EMDN</b>	<b>REF</b>
610075D01P087S0186CQ	A1099	24400, 24422, 24500, 24522, 25400, 25422, 25500, 25522, 27400, 27422, 27500, 27522
610075D01P087S0187CS	A1099	24600, 24742, 24752, 24762, 24852, 24862, 25600, 25742, 25752, 25762, 25852, 25862, 27600, 27762, 27862
610075D01P087S0346CN	A1099	24407, 24423, 24527, 27407, 27527, 27503
610075D01P087S0345CL	A1099	25720, 24720, 24763, 24867, 27767, 27867
610075D01P087S0360CG	A1099	25407, 25527
610075D01P087S0359CX	A1099	25767, 25867
610075D01P087S0347CQ	A1099	24403, 24503, 25403, 25423, 25503, 27403, 27423
610075D01P087S0348CS	A1099	24753, 24853, 24863, 25753, 25763, 25853, 25863, 27763, 27863

<b>Conform 2</b>		<b>GMDN 62526</b>
<b>Basic UDI</b>	<b>EMDN</b>	<b>REF</b>
610075D01P087S0235CC	A1099	24731, 24732, 24736, 24832, 25731, 25732, 25832, 27832
610075D01P087S0191CH	A1099	24735, 24833, 25733, 25833

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**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

<b>Clasificación</b>	(Anexo VIII): Clase I (Norma 1 y 4)
<b>Procedimiento de evaluación de la conformidad</b>	Clase I: No aplicable

<b>GMDN</b>	<b>Uso previsto</b>
<b>62525</b>	Los kits para ostomías contienen los dispositivos para ostomías que recogen el contenido de un estoma (p. ej., una colostomía, ileostomía o urostomía) o una abertura cutánea (p. ej., una herida o fístula). Los kits para ostomías también pueden contener accesorios para ostomías, cosméticos y productos de consumo que facilitan la aplicación del producto y el cuidado del estoma.
<b>62526</b>	Los kits para ostomías contienen los dispositivos para ostomías que recogen el contenido de un estoma (p. ej., una colostomía, ileostomía o urostomía) o una abertura cutánea (p. ej., una herida o fístula). Los kits para ostomías también pueden contener accesorios para ostomías, cosméticos y productos de consumo que facilitan la aplicación del producto y el cuidado del estoma.

Firmado por: Director de asuntos reglamentarios (es) Libertyville, IL, USA	<b>Fecha de decisión:</b>
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