

EU Declaration of Conformity

according to the REGULATION (EU) 2017/745 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL

*Class I Medical Device No.:*HDL-20210728-001

On the basis of the referenced test report(s), sample(s) tested of the below product have been found to comply with the standards harmonized with the directives listed on this verification at the time the tests were carried out. Other standards and Directives may be relevant to the product. This verification is part of the full test report(s) and should be read in conjunction with it <them>.

Applicant Name:	Hubei Hendry Medical Appliance Co.,Ltd.
Address:	No.2 & No.4 Building Yinhu Industry Park South Xiaohan Avenue, Development District 432000 Xiaogan City, Hubei Province PEOPLE'S REPUBLIC OF CHINA
Product Description:	Ostomy Bag and Accessories
Models/Type References:	Ostomy Bag/Ostomy paste/Ostomy Belt/Urine Bag/Ostomy powder/Stoma Care Accessories/Ostomy Skin Protective Film
EMDN code:	A100103
SRN:	CN-MF-000012337
Basic UDI-DI:	69351045One-pieceYN, 69351045Two-pieceEZ
GMDN:	64584
Brand Name(s):	/
Standard(s)/Directive(s):	Regulation (EU) 2017/745:2017 EN ISO 13485:2016 + AC:2018 + A11:2021 EN ISO 14971:2019 ISO/TR 24971: 2020 EN ISO 15223-1: 2021 EN ISO 10993-1:2020 EN ISO 10993-5:2009 EN ISO 10993-10:2023
Conformity assessment procedure:	Annex IV (II & III) of Regulation (EU) 2017/745
Classification	Class I according to rule 4
EU representative:	Share Info GmbH
Address:	Am Schulzentrum 12, 41564 Kaarst, Germany
SRN:	CN-MF-000012337

Signed on: May 08, 2025.

Place: Xiaogan, Hubei, China

Signature

陈雷

General Manager: Chen Lei

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