

CE Technical Documentation	Document No.: HH/CE-MDR-01-09	Edition: A/0	Page: 1 / 2
	Declaration of Conformity	Effective Date:2025-03-03	

Manufacturer	
Name and address:	Suzhou Hyha Medical Technology Development Co., Ltd. Add: No.8, Daming Road in High-Tech Industrial Park, Changshu Economic and Technological Development Zone, Suzhou, Jiangsu, 215500, China.
Contact information:	4-00115588-4
SRN:	CN-MF-000048261
European Authorized Representative	
Name and address:	MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
E-mail:	info@medpath.pro
SRN:	DE-AR-000000087
Device information	
Device Name:	Elastic Bandage
EMDN Code:	M030401 ELASTIC COMPRESSION BANDAGES
Basic UDI-DI:	69558238BDGS
Model and specification:	The device is self-adhesive and is divided into 33 models according to their length and width, as shown below, as follows: 2.5×100,4×100,2.5×200,5×200,7.5×200,8×200,10×200,12×200,15×200,5×300,7.5×300,10×300,15×300,6×200,5×450,7.5×450,8×450,10×450,12×450,15×450,8×600,5×600,7.5×600,10×600,15×600,16×600,18×600,20×600,5×800,3.8×800,3.8×700,3.8×600,3.8×450
Intended use:	Elastic Bandage used to provide binding force on wound dressings or limbs for bandaging and fixation purposes.
Risk of classification:	Class I Rule 4 (4.4, sentence 1) of Annex VIII of Regulation (EU) 2017/745
Conformity Assessment Procedure	Annex II+ Annex III of Medical Device Regulation (EU)2017/745
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We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards: EN ISO 13485:2016, EN ISO 15223-1:2021, EN ISO 20417-2021, EN ISO14971:2019, EN ISO 10993-1:2020, EN ISO10993-5:2020, ENISO10993-10:2023, EN ISO 10993-6:2016, EN ISO 10993-11:2018, EN ISO 10993-12:2012, EN ISO 10993-23:2021, EN ISO 10993-7:2008/AC:2009, EN ISO 11135: 2014, EN ISO 11737-1: 2018, EN ISO 11737-2: 2020	
We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.	

Suzhou 2025-03-03

Guibao Chen

Place, Date of Issue

Signature, Position

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