Declaration of Conformity

Manufacturer	
Name and address:	Shandong Haiyan Medical Manufacture Co., Ltd. No.1 Haiyan Road, Dongdu Town, Xintai City, 271200 Shandong, P.R. China.
Contact information:	Tel: 0086-0538-7372000 Fax: 0086-0538-7375111
SRN:	CN-MF-000001297
Trademark:	
European Authorized Representative	
Name and address:	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Contact information:	Peter Wei peter@lotusnl.com
SRN:	NL-AR-000000121
Notify Body	
Name:	TÜV Rheinland LGA Products GmbH
Address:	Tillystraße 2, 90431, Nürnberg, Germany

Digitally signed by Granaci Boris
Date: 2025.06.06 18:42:23 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Country:	Germany
Notified Body Identification Number:	CE 0197
（EC） Certificate(s)	XXXXXXXX
Expire date of the Certificate	YYYY-MM-DD
Device	
Device Name:	Wet pack products
EMDN Code:	D0702 ISOPROPYL ALCOHOL FOR THE DISINFECTION OF MEDICAL DEVICES
Basic UDI-DI:	69565997NPIA77 69565997SSIA8R 69565997TLIA7V
Model	P0-IA-1 P1-IA-1 P1-IA-2 P1-IA-3 P2-IA-1 P2-IA-2 TL-IA-3
Intended use:	The Wet Pack Products are intended for disinfecting non-invasive medical devices. The clinical usage scenario is in examination room of hospital and dental institutions, e.g. surface disinfection of examination chair, stethoscope desk, handle of air water dental syringe, etc. which are all

	with smooth surface under clean conditions. This device is for single use only.
Risk of classification:	Class IIa,Rule 16, Annex VIII, Chapter III of Medical Device Regulation (EU)2017/745
Conformity Assessment Procedure:	Annex IX of Medical Device Regulation (EU)2017/745
Technical Doc. No.	SDHY/CE-MDR-01,Version A/1

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 ISO 14971:2019, EN 62366-1:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 11138-1:2017, EN ISO 11138-2:2017, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN 17141:2020, EN ISO 10993-7:2008/AC:2009, EN ISO EN ISO 11137-1: 2015, EN ISO 11137-2: 2015, ASTM D4169-16:2016, ASTM F1980-16:2016, EN 14885:2018, EN 13624:2013, EN 13697:2015+A1:2019, EN 13727:2012+A2:2015

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.

Signature: Li Min Place: Taian

Position: Management representative Date: 2024.09.30