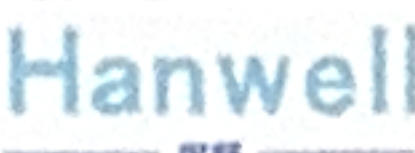


Manufacturer	
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SRN:	CN-MF-000035941
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EC Authorized Representative:	
Name and address:	MedPath GmbH Mies-van-der-Rohe-Strasse8,80807 Munich,Germany
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SRN:	DE-AR-000000087
Notify Body	
Name:	TÜV SÜD Product Service GmbH
Address:	Ridlerstraße 65 80339 MÜNCHEN
Country:	Germany
Notified Body Identification Number:	CE 0123
(EC) Certificate(s):	No. G20 124048 0002 Rev.00
Expire date of the Certificate:	2029.07.25
Medical device:	Anesthesia Mask
Model	HY-001-0, HY-001-1, HY-001-2, HY-001-3, HY-001-4, HY-001-5, HY-001-6, HY-002-0, HY-002-1, HY-002-2, HY-002-3, HY-002-4, HY-002-5, HY-002-6
EMDN Code:	R03010101 ANAESTHETIC FACE MASKS
Intended use	Anesthesia Mask used to connect the respiratory tract for anesthesia gas delivery, allowing patients to inhale anesthesia gas.
Basic UDI-DI	697583495ANEMT7
Risk of class	Class IIa Rule 2 1st paragraph + 1st indent, Annex VIII, Chapter III of Medical Device Regulation (EU)2017/745
Conformity Assessment Procedure:	Annex XI (Part A, Sec. 10) of Medical Device Regulation (EU)2017/745
Technical Document No.	HY/CE-MDR-02
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 ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-12:2012, EN ISO 10993-18:2020, EN 556-1:2001/AC2006, EN 62366-1:2015, ASTM D4169-16:2016, ASTM F1980-16:2016, ISO 18562-1:2024, BS EN ISO 18562-2:2020, BS EN ISO 18562-3:2020, BS EN ISO 18562-4:2020	
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.	
Ningbo 2024.07.28 Place, date	chenlitao 宁波汉跃医疗科技有限公司 GM Name and function