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CE Technical Documentation	EC DECLARATION OF CONFORMITY	Effective Date：2024-06-03	

Manufacturer	
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Notify Body	
Name:	TÜV SÜD Product Service GmbH
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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	chen li tao GM Name and function 宁波汉跃医疗科技有限公司 NINGBO HANYUE MEDICAL TECHNOLOGY CO., LTD