

# EC DECLARATION OF CONFORMITY

ACCORDING TO ANNEX II WITHOUT CHAPTER 4 OF COUNCIL DIRECTIVE 93/42/EEC

**MANUFACTURER: HEYER MEDICAL CO., LTD.**

ADDRESS: NO.2 Factory, Block B, No. 10 Chaobai Street, Yingbin Road West, Yanjiao Development Zone, 065201 Sanhe, Langfang City, Hebei Province, PEOPLE'S REPUBLIC OF CHINA

**EC REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)**

ADDRESS: Eiffestrasse 80, 20537 Hamburg, Germany

HEYER MEDICAL CO., LTD. DECLARE ON OUR OWN RESPONSIBILITY THAT:

NO.	MEDICAL DEVICE	TYPE/MODEL	GMDN CODE AND NAME
1	Ventilator	VS300S, VS500S, VS600S	14361, Neonatal intensive-care ventilator

CLASSIFICATION: CLASS IIb RULE 11

CONFORMITY ASSESSMENT ROUTE: ANNEX II WITHOUT CHAPTER 4

WE HEREWITH DECLARE THAT ABOVE MENTIONED PRODUCT(S) MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES, INCLUDING THE REQUIREMENTS FROM ARTICLE 120(3) OF EU 2017/745, MDR ON MAY 26<sup>TH</sup> 2022. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GmbH

ADDRESS: RIDLERSTRASSE 65 80339 MÜNCHEN

EC CERTIFICATE: No. G1 002954 0002 Rev.01


Valid from: 2020-02-25

Valid until: 2023-07-08



PERSON RESPONSIBLE  
FOR REGULATORY COMPLIANCE:  
PLACE:

SUN XIAOFENG  
LANGFANG CITY, HEBEI PROVINCE

SIGNATURE:   
DATE: 