

EC DECLARATION OF CONFORMITY

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

MANUFACTURER: BEIJING AEONMED CO., LTD.

ADDRESS: Room 405, Basement 1 to 4th Floor of 901 Unit, Building 9, No.26 Outer Ring West Road, Fengtai District, 100070 Beijing, PEOPLE'S REPUBLIC OF CHINA

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

ADDRESS: Eiffestrasse 80, 20537 Hamburg, Germany

BEIJING AEONMED CO., LTD. DECLARE ON OUR OWN RESPONSIBILITY THAT:

NO.	MEDICAL DEVICE NAME	TYPE/ MODEL	GMDN CODE & NAME
1	Ventilator	Shangrila510S	36289 Transport electric ventilator

CLASSIFICATION: 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 26TH 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: G1 065725 0019 Rev.04

Valid from: 2021-05-21

Valid until: 2024-05-26



PERSON RESPONSIBLE
FOR REGULATORY COMPLIANCE:

PLACE:

SIGNATURE:

DATE: 2023.2.15

SUN XIAOFENG

BEIJING

