



DECLARATION OF CONFORMITY

Manufacturer

Jiangsu Weikang Jiejing Medical Apparatus Co., Ltd.

Add: No. 18, Wenzhou Road, Economic Development Zone, Shuyang, Jiangsu, China
Tel: 0527-80817126 80817127
SRN: CN-MF-000002179

whose single Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175
Fax: +49-40-255726
Dimdi No.: DE/0000040627
E-mail: shholding@hotmail.com
SRN: DE-AR-000000001

We, the manufacturer, herewith declare that the products:

Product Name	Catalog #	Basic UDI-DI	UMDNS CODE	Device Class	Intended Use
Hyperventilation Mask	HBM06-HV2 000E	0697030 4310331	12450	Class I, according to Annex VIII of the MDR 2017/745	Used as an Accessory of Non-rebreathing Mask which is used for oxygen inhalation of high-concentration

meet the provisions of Medical Device Regulation (MDR) 2017/745 which apply to them.

The product concerned has been designed and manufactured under a QMS (Quality Management System) according to Annex II and Annex III of Medical Device Regulation (MDR) 2017/745.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Medical Device Regulation (MDR) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Camel Zhou

Signature:

Position held in the company: VP

Date: Jun. 2nd, 2022

Place: Jiangsu, China

Jiangsu Weikang Jiejing Medical Apparatus Co., Ltd.