



BAISHENG MEDICAL CO.,LTD.

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EU DECLARATION OF CONFORMITY

Baisheng Medical Co., Ltd. with SRN number: CN-MF-000024558 declares under his sole responsibility that the products listed in annexes of the present declaration have been manufactured according to requirements of the **Regulation (EU) 2017/745 on Medical Devices** and meet requirements set in the General Safety and Performance Requirements of the Annex I of above-mentioned Regulation.

Technical documentation, established in accordance with the corresponding annexes of the Regulation (EU) 2017/745 on medical devices, is updated and located in our facilities. We are in position to submit these documents in case of Notified Body or Competent Authority requirement.

This declaration applies to design, manufacturing, and final control of medical devices. Validity of the present declaration is subject to the expiration of the corresponding EC certificates for different products.

Jiangmen, on February 23th 2024

Chen Xi
General Manager

List of self-certified products

Defibrillation Electrodes	
Description	Set of two multi-function electrodes. Adult. Pre-connected cable.
Commercial brand	OBS
Models	OBS-DE/P, OBS-DE/P2/a, OBS-DE/P3/a, OBS-DE/P4/a, OBS-DE/M, OBS-DE/ME/a, OBS-DE/W, OBS-DE/Z1, OBS-DE/Z2, OBS-DE/NK1/a, OBS-DE/NK2/a, OBS-DE/CU1/a, OBS-DE/CU2/a, OBS-DE/MP/a, OBS-DE/SC1/a, OBS-DE/SC2/a,
Classification	
Product class I - Non-sterile. According to Rule 1 of Annex VIII of Regulation (EU) 2017/745.	
Basic UDI-DI	69394115OBSDEUN
UMDNS	11130
GMDN	41771
EMDN	C020401 (EXTERNAL CARDIOVERSION DEFIBRILLATOR ELECTRODE PADS)
MDN CODE	MDN 1201
MDS CODE	MDS 1011
Standards applied	
EN ISO 13485:2016/A11:2021// EN ISO 14971:2019+A11:2021// EN ISO 15223-1:2021 // ISO 20417: 2021 // EN ISO 10993-1: 2020// EN ISO 10993-5:2009// EN ISO 10993-10: 2023// EN ISO 10993-23: 2021// EN 60601-1:2006+A1:2013+A2: 2021// EN 60601-1-2: 2015/A1: 2021// EN 60601-2-4:2010+A1: 2018// EN 60601-1-12:2015/A1:2020// EN 62366-1:2015/A1:2020.	
Additional information	
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