



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Cert GmbH,
Harffstr.47,40591 Düsseldorf, Germany
SRN: DE-AR-000010869

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971:2019
EN ISO 15223-1:2021
EN ISO 20417:2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document CEMDR-Y090699-14.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: Ningbo Albert Novosino Co.,Ltd.
Address: No.1206 Qingfeng West Road, Sanqishi Town, Yuyao City, Zhejiang Province, 315412, P. R. China
SRN: CN-MF-000008571

Product Information

Name: Waterproof Cast Cover
Model: Arm-XXXS, XXS, XS, S, M, L, XL, XXL, XXXL, Leg-XXXS, XXS, XS, S, M, L, XL, XXL, XXXL, Elbow-XXXS, XXS, XS, S, M, L, XL, XXL, XXXL
EMDN: Y090699
Basic UDI:
Classification: Class I, According to Rule 4, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: *Jirone Zhang* Date: 2024.2.19
Position: GM Place: Zhejiang/China