



EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices



Ningbo Dacheng Medical Instrument Co., Ltd.

No.1, BLD.12, Tanxiang South Road, Yuelong
District, Ninghai County, Ningbo, Zhejiang Province, China

Manufacturer SNR: CN-MF-000009654

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

European Representative:

EC REP

MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

EU REP SRN:

DE-AR-0000000087

Product Name:

Air Cell Cushion

Product Code / Catalog No.:

(XX=AC05 or AC06)

(XX=AC07 or AC09)

DCM-ACXX-1V2525, DCM-ACXX-1V2530, DCM-ACXX-1V3030;
DCM-ACXX-1V3035, DCM-ACXX-1V3535, DCM-ACXX-1V3540;
DCM-ACXX-1V4040, DCM-ACXX-1V4540, DCM-ACXX-1V4545;
DCM-ACXX-1V5045, DCM-ACXX-1V5050.

Basic UDI:

697533875AC001E3

Classification acc. to MDR Ax. VIII:

Class 1, rule 1

Applied Standard & Common Specification: EN ISO10993-1:2009 ; EN ISO10993-5: 2009 ;
EN ISO10993-10:2010

权宁珠

Quan Ningzhu / General Manager

Ninghai, March. 30th, 2024



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European Representative:

EC REP

MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

EU REP SRN:

DE-AR-000000087

Product Name:

Gel Working Cushion

Product Code / Catalog No.:

DCM-GW01, GW02, GW03, GW04, GW05

Basic UDI:

697533875GW001LH

Classification acc. to MDR Ax. VIII:

Class 1, rule 1

Applied Standard & Common Specification:

EN ISO10993-1:2009 ; EN ISO10993-5: 2009 ;
EN ISO10993-10:2010

Conformity Assessment Procedure:

Annex II + Annex III of MDR

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Quan Ningzhu / General Manager

Ninghai, March. 30th, 2024