



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:



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

EU REP SRN:

DE-AR-000000087

Part Name:

As the Annex

Part Code / Catalog No.:

As the Annex

Basic UDI:

As the Annex

Classification acc. to MDR Ax. VIII:

Class 1, rule 1

Applied Standard & Common Specification: EN ISO10993-1:2020; EN ISO10993-5: 2009;
EN ISO10993-10:2023; EN ISO10993-23:2021

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Quan Ningzhu / General Manager

Ninghai, Jun. 30th, 2024

Part Name: Prosthetic Part & Basic UDI: 697533875PP001N3
Part Code / Catalog No. is as the follows

- Carbon Fiber Foot:

CFF01, CFF02, CFF03, CFF04, CFF05, CFF06.

- Knee Joint & Hip Joint:

PKJ-A01, PKJ-A02, PKJ-A03, PKJ-A04, PKJ-A05, PKJ-A06, MKJ-A01, MKJ-A02, MKJ-A03, MKJ-A04, MKJ-A05, MKJ-A06, MKJ-A07, MKJ-A08, MKJ-A09, MKJ-A10, MHJ-A01, MHJ-A02, MKJ-P01, MKJ-P02, MHJ-P01.

- Shuttle Lock & Lock Pin:

SL-M01A, SL-F02A, SL-B03A, SL-M04S, SL-F05S, SL-M06A, SLP-48S, SLP-58S, SLP-68S, SLP-78S, SLP-88S, SLP-98S.

- Tube Clamp Adapter:

KRA-R01S, TCA-F01S, TCA-F01A, TCA-F02S, TCA-F02A, TCA-F03S, TCA-F04S, ATCA-F05S, STCA-F06S, ADTA-F07S, SATA-F08S, TCA-M09S, STCA-M10S, ATA-MF11S, SATA-MF12S, TCA-M13S, DPA-M14S, ITA-F15S, ITA-F16S, ITA-F17S, ITA-M18S, LD-01R.

- Foot Adapter:

FA-M01S, FA-M01A, FA-M02S, FA-M03S, FA-M04S, FA-M05S, FA-S06S, FA-T07S.

- Tube Adapter:

ATA01-32S, ATA01-40S, ATA01-55S, ATA01-70S, ATA02-32S, ATA02-40S, ATA02-55S, ATA02-70S, ATA03-32S, ATA03-40S, ATA03-55S, ATA03-70S, FTA-32S, FTA-45S, FTA-60S, FTA-75S, FTA-90S, FTA-32A, FTA-45A, FTA-60A, FTA-75A, MFTA-32S, MFTA-45S, MFTA-60S, MFTA-75S, MFTA-45A, MFTA-60A, MFTA-75A, DETA-32S, DETA-45S, DETA-60S, DETA-75S, DETA-32A, DETA-45A, DETA-60A, MFTA-65A, DETA-75A, SMFTA-45S, SMFTA-50S, SMFTA-60S, SMFTA-75S, SDETA-45S, SDETA-50S, SDETA-60S, SDETA-75S.

- Socket Adapter:

SA-M01S, SA-M01A, ASA-M02S, SA-F03S, ASA-F04S, SA-M05S, ASA-M06S, ASA-F07S, ASA-F08S, ASA-L09S, ASA-L10S, ASA-M11S, ASA-F12S, SA-M13S, SA-F14S, ASA-F15S, SA-T16S, SA-F17S, SA-M18S, ASA-F19A, ASA-F20A, ASA-F21A, SA-P22A, SA-T23A, SA-F24A, SA-T25A, SA-F26A, SA-T27A, SA-F28A, SA-T29A.

- Pediatric Adapter:

PTCA-F01S, PTCA-M02S, PTCA-F03S, PFA-M01S, PFA-M01A, PFA-T02S, PSA-M01S, PSA-F02S, PASA-M03S, PASA-F04S, PSA-M05S, PSA-F06S, PASA-M07S, PASA-F08S, PSA-F09S, PMFTA-22S, PMFTA-30S, PMFTA-38S, PDETA-22S, PDETA-30S, PDETA-38S, PFTA-38S, PFTA-46S, PFTA-54S, PFTA-62S.

- Pylon & Tube:

AP-220C1, AP-420C1, AP-220C2, AP-420C2, AP-220S1, AP-420S1, AP-220S2, AP-420S2, AP-220A1, AP-420A1, AP-220A2, AP-420A2, AP-220SP, AP-420SP, AP-340S, PP160R, PP310R, AT-200C, AT-400C, AT-200S, AT-400S, AT-200B, AT-400B.

Part Name: TPE Gel Liner & Basic UDI: 697533875PL001M7
Part Code / Catalog No. is as the follows

- Locking Type(Skin Color):

DKC1619-L3S, DKC2023-L3S, DKC2427-L3S, DKC2831-L3S, DKC3235-L3S, DKC3639-L3S, DKC4045-L3S; DKC1619-L6S, DKC2023-L6S, DKC2427-L6S, DKC2831-L6S, DKC3235-L6S, DKC3639-L6S, DKC4045-L6S.

- Locking Type(Coffee Color):

DKC1619-L3C, DKC2023-L3C, DKC2427-L3C, DKC2831-L3C, DKC3235-L3C, DKC3639-L3C, DKC4045-L3C; DKC1619-L6C, DKC2023-L6C, DKC2427-L6C, DKC2831-L6C, DKC3235-L6C, DKC3639-L6C, DKC4045-L6C.

- Cushion Type(Skin Color):

DKC1619-C3S, DKC2023-C3S, DKC2427-C3S, DKC2831-C3S, DKC3235-C3S, DKC3639-C3S, DKC4045-C3S; DKC1619-C6S, DKC2023-C6S, DKC2427-C6S, DKC2831-C6S, DKC3235-C6S, DKC3639-C6S, DKC4045-C6S.

- Cushion Type(Coffee Color):

DKC1619-C3C, DKC2023-C3C, DKC2427-C3C, DKC2831-C3C, DKC3235-C3C, DKC3639-C3C, DKC4045-C3C; DKC1619-C6C, DKC2023-C6C, DKC2427-C6C, DKC2831-C6C, DKC3235-C6C, DKC3639-C6C, DKC4045-C6C.

Part Name: PU Foot & Basic UDI: 697533875PF001KV
Part Code / Catalog No. is as the follows

- Pediatric(Children's) Foot Shell:

PFS-P15R, PFS-P16R, PFS-P17R, PFS-P18R, PFS-P19R; PFS-P15L, PFS-P16L, PFS-P17L, PFS-P18L, PFS-P19L.

- Adult Foot Shell:

PFS-A20R, PFS-A21R, PFS-A22R, PFS-A23R, PFS-A24R, PFS-A25R, PFS-A26R, PFS-A27R, PFS-A28R, PFS-A29R; PFS-A20L, PFS-A21L, PFS-A22L, PFS-A23L, PFS-A24L, PFS-A25L, PFS-A26L, PFS-A27L, PFS-A28L, PFS-A29L.

- Pediatric(Children's) Sach Foot:

PSF-P15R, PSF-P16R, PSF-P17R, PSF-P18R, PSF-P19R; PSF-P15L, PSF-P16L, PSF-P17L, PSF-P18L, PSF-P19L.

- Adult Sach Foot:

PSF-A20R, PSF-A21R, PSF-A22R, PSF-A23R, PSF-A24R, PSF-A25R, PSF-A26R, PSF-A27R, PSF-A28R, PSF-A29R; PSF-A20L, PSF-A21L, PSF-A22L, PSF-A23L, PSF-A24L, PSF-A25L, PSF-A26L, PSF-A27L, PSF-A28L, PSF-A29L.

- Axis Foot with Single Hole:

PASF-A21R, PASF-A22R, PASF-A23R, PASF-A24R, PASF-A25R, PASF-A26R, PASF-A27R, PASF-A28R, PASF-A29R; PASF-A21L, PASF-A22L, PASF-A23L, PASF-A24L, PASF-A25L, PASF-A26L, PASF-A27L, PASF-A28L, PASF-A29L.

- Axis Foot with Double Hole :

PADF-A21R, PADF-A22R, PADF-A23R, PADF-A24R, PADF-A25R, PADF-A26R, PADF-A27R, PADF-A28R, PADF-A29R; PADF-A21L, PADF-A22L, PADF-A23L, PADF-A24L, PADF-A25L, PADF-A26L, PADF-A27L, PADF-A28L, PADF-A29L.