

EU DECLARATION OF CONFORMITY

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

Manufacturer: Carclo Technical Plastics (Taicang) Co.,Ltd
No.8 Xi Xin Road, Chengxiang Town, Taicang, Jiangsu
Province, P.R China,215411.

Trademark: /

SRN: Not available yet

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

SRN: DE-AR-000000087

Trade name: /

Product name: HI-POWER

Product code / Catalogue number: See attachment

Basic UDI: 6976289704208GW

Classification acc. to MDR Ax. VIII: Class 1, rule 1

Applied Standard & Common Specification: ENISO8980-1:2017
ENISO8980-3:2022; ENISO8980-4:2006

Conformity assessment procedure: Annex II + Annex III of MDR;

CE certificate No.: N.A.

Name and ID of the Notified Body: N.A.

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.

Yin Guihua
Quality Manager



Taicang, Nov. 05 . 2024

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Attachment

| Part NO# | Part Name | Part NO# | Part Name |
|----------|--------------------------------------|----------|--------------------------------|
| 4206 | HIPOWER FIXED STAND 6X 20D | 5204 | HI POWER HAND MAG 4X |
| 4208 | HIPOWER FIXED STAND 8X 28D | 5204/05 | RS HI POWER HAND MAG 4X |
| 4210 | HIPOWER FIXED STAND 10X 36D | 5206 | HI POWER HAND MAG 6X/20D |
| 4212 | HIPOWER FIXED STAND 12X 44D | 5206/05 | RS HI POWER HAND MAG 6X |
| 4215 | HIPOWER FIXED STAND 15X WT PCH | 5213 | HI POWER TILT STAND MAGNIFIER |
| 5123 | HI-POWER ASPH STAND READER | 5214 | HI POWER TILT STAND MAG 4X 12D |
| 5203 | HI-POWER HAND MAG WITH POUCH | 5215 | HI POWER RECT HAND MAG 1.7/2.8 |
| 5203/05 | RS HI POWER HAND MAG 3X | 5216 | HI POWER RECT HAND MAG 2.3X5.2 |
| 9213 | ILLUMINATED TILT STAND MAGNIFIER(3X) | | |
| 9214 | ILLUMINATED TILT STAND MAGNIFIER(4X) | | |

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Yin Guirua,
Quality Manager



Taicang, Nov.05. 2024