



Erklärung Declaration

Die Firma / The manufacturer

Sundo Homecare GmbH
Bahnhofstr. 13
30916 Isernhagen

erklärt hiermit, um welche Produkte es sich bei der nachfolgenden Konformitätserklärung handelt
hereby declares which products are the subject of the following declaration of conformity

Sundo Artikel-Nr. Item No.:	Bezeichnung / Description	UDI-Nr. / UDI-No.	Basic UDI-DI
10200	Duschhocker mit Armlehne, Hygieneausschnitt	06974522420001	69745224200017T
10210	Duschstuhl mit Arm- und Rückenlehne, Hygieneausschnitt	06974522420018	69745224200188C
10220	Duschstuhl faltbar, mit Arm- und Rückenlehne,Hygieneausschnitt	06974522420025	697452242002589
11250	Badewannensitz mit Hygieneausschnitt, Rückenlehne	06974522420049	69745224200498P
11252	Badewannensitz mit Hygieneausschnitt	06974522420056	69745224200568L

EU Declaration of Conformity

Manufacturer: Shanghai Maxcare Medical Device Co., Ltd.
No. 93, Dianxing Rd., Dianshanhu Town, Kunshan City, Jiangsu
Province, P. R. China, 215345

SRN: CN-MF-000010578

European
Representative: Riomavix Sociedad Limitada
Calle de Almansa 55, 1D, Madrid 28039 Spain

SRN: ES-AR-000001202

Product Name: Shower Chair

GMDN Code: 34936

UMDN Code: 10802

UDI: (01)06974522420001/(01)06974522420018/(01)06974522420025/
(01)06974522420032/(01)06974522420049/(01)06974522420056/
(01)06974522420063

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith under our sole responsibility declare that above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

Shanghai Maxcare Medical Device Co., Ltd. is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 14971:2019, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM D4169-2016, MDCG 2019-15.

Signature:

Name:

Position:

Place/date



General Manager

Shanghai City, 2024-02-28