



Declaration of Conformity/ GB, IR, MAL

Manufacturer, Supplier

iTD GmbH
Sportplatzstraße 3, 84381 Johanniskirchen
Deutschland/Germany

The products

Mobile equipment carts:

Mini-Rollstand 2.0/ elo-cart, uni-cart, vexio-cart, vexio-cart "Plus", pro-cart, duo-cart, classic-cart, compact-cart, endo-cart, symbio-cart

Stationary carrier systems:

modul-port, flexion-port, lf-port, rm-port, mf-port

1. Conformity assessment procedure

(Types and part numbers see attachment 1 of this declaration)

The products meet the applicable sections of the "General safety and performance requirements" according to Annex I of the EU Regulation 2017/745 (MDR).

In accordance with Annex IX, we apply the conformity assessment procedure for Class I and other products and issue the declaration of conformity for our products as manufacturer.

The applicable sections of IEC 60601-1:2005 + A1:2012 + A2:2020, DIN EN 60601-1:2022-11 (German version) are used as a basis.

2. Classification

In accordance with Annex VIII of Regulation (EU) 2017/745, the iTD products are classified as non-sterile and non-invasive medical devices and thus assigned to Class I in accordance with Rule 1 of this regulation.

3. RoHS Guideline – Restriction of certain hazardous substances

Conformity to EU-Directive 2011/65EU and 2015/863/EU

All iTD products, including all enclosed parts and components, comply with the requirements of EU Directive 2011/65/EU and Directive 2015/863/EU with regard to the restriction of individual hazardous substances.)

4. UDI/EUDAMED

UDI/EUDAMED is currently not available. Already generated codes: see attachment 2 of this CE declaration

We are registered with GS1 and can already assign GTIN numbers.

Our Global Location Number (GLN) is: 40 56634 00000 4.

5. Validity

This declaration loses its validity in the event of improper use of the medical device and in the event of making changes to the medical device that are not agreed with the manufacturer.

Date of issue

iTD GmbH

Johanniskirchen, Stand: 12.10.2023
Location, date



Andreas Hager; Director of Global Engineering
Legally binding signature

The producer is exclusively responsible for the declaration of conformity.

This declaration does not contain any assurance of product attributes based on the product-liability-law.



Attachement 1

MD Category: MP Kategorie:	Medical Device Name Medizinprodukt Bezeichnung	Item No. (REF) Art.Nr.	Associated product line Produktlinie
Basic-UDI-DI: 04			
4056634classic-cartVN	ITD 00 PLAIN CART KU3879800 W.REAR PANEL	KU.3879.800	classic-cart
4056634classic-cartVN	ITD 00 PLAIN CART KU4237800 SCHUKO 19MON	KU.4237.800	classic-cart
4056634classic-cartVN	ITD 00 PLAIN CART KU4238800 SCHUKO PANEL	KU.4238.800	classic-cart
4056634compact-cart2E	ITD 03 KU2709800	KU.2709.800	compact-cart
4056634compact-cart2E	ITD 03 ISO KU2710800	KU.2710.800	compact-cart
4056634compact-cart2E	ITD 03 PLUS KU2706800	KU.2706.800	compact-cart
4056634compact-cart2E	ITD 03 ISO PLUS KU2707800	KU.2707.800	compact-cart
4056634compact-cart2E	ITD 03 EUS ISO KU2711800	KU.2711.800	compact-cart
4056634compact-cart2E	ITD 03 EUS ISO PLUS KU2708800	KU.2708.800	compact-cart
4056634compact-cart2E	ITD 04 ISO KU5910800	KU.5910.800	compact-cart
4056634compact-cart2E	ITD 04 ISO PLUS KU5908800	KU.5908.800	compact-cart
4056634compact-cart2E	ITD 04 EUS ISO PLUS KU5912800	KU.5912.800	compact-cart
4056634compact-cart2E	ITD 04 EUS ISO KU5911800	KU.5911.800	compact-cart
4056634compact-cart2E	ITD 04 KU5909800	KU.5909.800	compact-cart
4056634compact-cart2E	ITD 04 PLUS KU5907800	KU.5907.800	compact-cart
4056634uni-cartPK	ITD 03 GAS KD8580801	KD.8580.801	uni-cart
4056634uni-cartPK	ITD 03 SONO KD7369801	KD.7369.801	uni-cart
4056634flexion-portF7	ITD HA2234903 FLEXION-PORT 3-10 kg	HA.2234.903	flexion-port

4056634flexion-portF7	ITD HA2236903 FLEXION-PORT 8-14 kg	HA.2236.903	flexion-port
4056634ITD-accessoriesWH	ITD GW0160991 GAS BOTTLE HOLDER 3/5/10L	GW.0160.991	compact-cart Zubehör
4056634ITD-accessoriesWH	ITD GW0890991 GAS BOTTLE HOLDER 10-20L	GW.0890.991	compact-cart Zubehör
4056634compact-cart2E	ITD CC4520817 W450 SHELF FOR ITD-03	CC.4520.817	compact-cart Zubehör
4056634ITD-accessoriesWH	ITD GW9801991 STD.RUNNER FIXATION ITD02	GW.9801.991	compact-cart Zubehör
4056634ITD-accessoriesWH	ITD KU4470999 ARM MINI PROBE WITH CLAMP	KU.4470.999	compact-cart Zubehör
4056634classic-cartVN	ITD KD7850803 KEYBOARD HOLDER ITD03	KD.7850.803	classic-cart Zubehör
4056634ITD-accessoriesWH	ITD CC0312805 SIDE SHELF FOR ITD-03	CC.0312.805	compact-cart Zubehör
4056634classic-cartVN	ITD GW5001827 SHELF FOR ITD00 PLAIN	GW.5001.827	classic-cart Zubehör
4056634ITD-accessoriesWH	ITD GW9803999 WALL HOLDER FOR ENDOSCOPES	GW.9803.999	classic-cart Zubehör
4056634ITD-accessoriesWH	ITD KD6558999 TWIN ENDOSCOPE HOLDER	KD.6558.999	classic-cart Zubehör
4056634ITD-accessoriesWH	ITD KU2278991 Cross Beam ITD03 B450	KU.2278.991	classic-cart Zubehör
4056634ITD-accessoriesWH	ITD FC0221991 EQUIPMENT FIXING	FC.0221.991	classic-cart Zubehör
4056634ITD-accessoriesWH	ITD ZV9286991 PLASTIC BOX WITH MOUNT.BR.	ZV.9286.991	classic-cart Zubehör
4056634ITD-accessoriesWH	ITD ZV9986999 DRAIN GLASS	ZV.9986.999	classic-cart Zubehör
4056634ITD-accessoriesWH	ITD GW0870991 Endoscope holder dual	GW.0870.991	classic-cart Zubehör
4056634ITD-accessoriesWH	ITD GW9882999 HOSE HOLDER	GW.9882.999	classic-cart Zubehör

EB atitikties deklaracija / LV



Gamintojas arba tiekėjas

iTD GmbH
Sportplatzstraße 3, 84381 Johanniskirchen
Vokietija /Germany

Gaminiai

Mobilieji įrangos vežimėliai:

Mini-Rollstand 2.0/ elo-cart, uni-cart, vexio-cart, vexio-cart "Plus", pro-cart, duo-cart, classic-cart, compact-cart, endo-cart, symbio-cart

Stacionarios laikymo sistemos:

modul-port, flexion-port, lf-port, rm-port, mf-port

1. Atitikties vertinimo procedūra

(Tipai ir dalių numeriai nurodyti šios EB atitikties deklaracijos 1 priede)

Gaminiai atitinka Reglamento (ES) 2017/745 I priedo „Bendrieji saugos ir veiksmingumo reikalavimai“ taikomas skiltis.

Pagal IX priedo nuostatas taikome I klasės ir kitų gaminių atitikties vertinimo procedūrą, ir išduodame atitikties deklaraciją kaip gamintojas.

Kaip pagrindas naudojami IEC 60601-1:2005 + A1:2012 + A2:2020, DIN EN 60601-1:2022-11 (vokiškos versijos) skirsniai.

2. Klasifikavimas

Pagal Reglamento (ES) 2017/745 VIII priedo nuostatas iTD gaminiai klasifikuojami kaip nesterilios ir neinvazinės medicininės paskirties priemonės, todėl pagal šio reglamento 1 taisyklę priskiriami I klasei.

3. RoHS direktyva – tam tikrų pavojingų medžiagų naudojimas

Atitiktis direktyvoms 2011/65/ES ir 2015/863/ES

Visi iTD gaminiai, įskaitant visas jų vidines dalis ir komponentus, atitinka 2011/65/ES ir 2015/863/ES direktyvų reikalavimus dėl tam tikrų pavojingų medžiagų naudojimo.

4. UDI/EUDAMED

UDI/EUDAMED šiuo metu nėra. Jau sukurti kodai: žr. šios deklaracijos 2 priedą

Mes esame GS1 narys ir jau galime priskirti GTIN numerius.

Mūsų pasaulinis lokacijos numeris (GLN) yra: 40 56634 00000 4.

5. Galiojimas

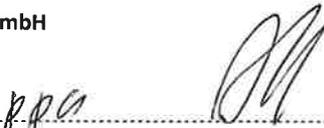
Ši deklaracija nustoja galioti netinkamai naudojant medicininės paskirties priemonę arba pakeitus jos konstrukciją, prieš tai nesuderinus keitimo su gamintoju.

Išdavimo data

iTD GmbH

Johanniskirchen, Data: 12.10.2023

Vieta, data


.....
Andreas Hager, Director of Global Engineering
Legally binding signature

Už šią atitikties deklaraciją atsako tik gamintojas.

Šioje deklaracijoje nepateikta jokių garantijų dėl gaminio savybių pagal atsakomybės už gaminius teisės aktus.

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