Berchtold GmbH & Co. KG
Ludwigstaler Straße 25
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T: (07461)-181-0, Fax: (07461)-181-100

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Declaration Of Conformity

European Medical Device Regulations EEC 2017/745/EC

DoC Number: DECL10373, Rev. D

Manufacturer:	Registration Number
Berchtold GmbH & Co. KG Ludwigstaler Straße 25 78532 Tuttlingen Germany Tel: (07461)-181-0, Fax: (07461)-181-100	Registration Number: SX 1727994-1 Single Registration Number: Not Applicable

Product Family Name: **(See Annex: Product List)**

Product Class and Rule: **(See Annex: Product List)**

(1) According to Annex II and Annex III of the Medical Device Regulation EEC 2017/745, we hereby declare under our sole responsibility that these products conform with the relevant provisions of the Medical Device Regulation EEC 2017/745.

Each of the listed and CE-marked products in the appendix has been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Annex I in the Medical Device Regulations 2017/745 prior to being placed on the market. This declaration applies to CE Marked devices produced after the date issuance of this declaration.

This declaration is supported by Quality System Certificate for the products concerned. The conformity to quality assurance set out in the said EN ISO 13485:2016 Conformity Certificate number SX 1727994-1, issued and delivered by TUV Rheinland, LGA Products GmbH, Tillystraße 2, 90431 Nuremberg, Germany.

(2) We declare, under our sole responsibility, that the products specified in the Annex- Product list also conform to the following regulations and directives. All supporting information is retained under the control of the Legal Manufacturer.

- IEC 63000, Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances; RoHS2 Directive, 2011/65/EU and the RoHS3 Delegated Directive, 2015/863/EU *(where appropriate)*. This statement is applicable only to those part numbers in the annexed product list for which RoHS is applicable.

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Issue date: 28. Jun. 2021
Effective Date: 28. Jun. 2021
Place of issue: Tuttlingen, Germany

Signed for and behalf of Berchtold GmbH & Co. KG by:

28-Jun-2021

Electronically signed by:
Volker Hornscheidt
Reason: I approve this document
Date: Jun 28, 2021 14:36 GMT+2

Date

Volker Hornscheidt
Director Regulatory Affairs & Quality Systems

This declaration is valid until: *13-AUG-2023*

Annex – Product List

This product list belongs to the Declaration of Conformity identified by Berchtold GmbH & Co. KG and specifies the CE marked products concerned that Berchtold GmbH & Co. K intends to distribute in conformity with the provisions of Medical Device Regulations (MDR) EEC 2017/745/EC concerning medical devices and Council Directive 2011/65/EU concerning electrical and electronic equipment.

The following list identifies the products by Catalogue number and type.

Product Family Name: *Surgical Tables and Accessories*

Catalogue Number	Product Name	Basic UDI-DI	Technical File / Documentation	Product Class and Rule
OPE10000	Berchtold Operon® D850 Surgical Table	0885825000753SB	TF10469	Class I (Rule 13)
OPE10000	Berchtold Operon® D820 Surgical Table	0885825000753SB	TF10469	Class I (Rule 13)
OPE10000	Berchtold Operon® D760 Surgical Table	0885825000753SB	TF10469	Class I (Rule 13)

Refer to the Technical File / Documentation for Intended Purpose and List of Applied Standards of the device.