Baxter

EU Declaration of Conformity for Medical Devices

This is a Declaration of Conformity made under article 19 of Regulation 2017/745/EU (MDR).

Manufacturer Name:	Baxter Medical Systems GmbH + Co. KG
Manufacturer's Address:	Carl-Zeiss-Str. 7-9 07318 Saalfeld Germany
Single Registration Number:	DE-MF-000005071
Product Description:	TruLight 1000 - Examination Light
Product Name/ Reference Number:	TruLight 1000 / ceiling 4058110 TruLight 1000 / wall 4058120 TruLight 1000 / mobile 4058130 TruLight 1000 / pendant 4058140
Intended Purpose:	The examination light is intended to be used to provide visible illumination of the area to be examined.
Classification:	Class I, Rule 13, Annex VIII
Conformity assessment procedure:	Annex II + III
GMDN Code and Term:	12276 Fixed examination/treatment room light
UMDNS Code:	12-276
EMDN Code:	Z12010701
Basic-UDI-DI:	0887761GMN000033U3
Valid until:	This manufacturer's declaration of conformity is valid from the date of validity and remains valid until it is superseded or withdrawn due to product change.

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EC Certificate of Conformity Number: Not applicable

EC Certificate of Conformity Expiry date: Not applicable

Notified Body Name and Address: Not applicable

Notified Body Identification Number: Not applicable

Common Specifications Applied: Not applicable
This section should include reference to Common Specifications only. Standards or other regulations applicable to the products should not be included in this section.

We declare under our sole responsibility that the listed product(s) conform to the applicable provisions of above-mentioned Common Specification(s) and the below Regulation(s):

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restrictions of use of certain hazardous substances in electrical and electronic equipment (RoHS)

COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

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This declaration shall be void whenever the medical device is used contrary to the intended purpose, and when any modification is made to the medical device without prior approved by the manufacturer.

Saalfeld, 29. Dez. 2022

CE

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Marco Dähnert
Assoc. Director Quality Assurance
Person Responsible for Regulatory Compliance

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Bernd Schell
Director Regulatory Affairs GSS

Validity date from: 19th January 2023

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Document type for QSD: F

General: Before using the document, make sure you are using the latest version.

1 Change history

Version	Author	Change
01	Jonathan von Wittern	Initialization
02	Mathias Heller	Change of signatories (PRRC and RA); change of owner
03	Norman Martin	Adding SRN assigned 26-May-2021
04	Mathias Heller	Adding Delegated Directive (EU) 2015/863 (RoHS 3)
05	Mathias Heller	Changed header and font, Removed Directives WEEE, REACH, RoHS, LVD, EMC Added Intended Use, Classification Rule and Conformity Assessment Route Annex Replaced EN 50581 by EN IEC 63000
06	Andreas Werry	Transfer DoC to Baxter with new template according to ECN 211127-511pr Radio Directive deleted

Signed by /
Podpisano przez:

Tomasz Zalewski

Date / Data:
2024-04-30
12:51