

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

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	This manufacturer's declaration of conformity is valid from the date of validity and remains valid until it is superseded or withdrawn due to product change.

**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)

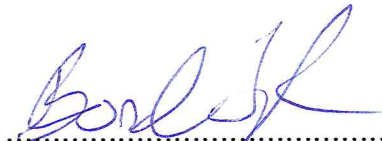
COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

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, 23. Dec. 2022

A handwritten signature in blue ink, appearing to read 'M. Dähnert', positioned above a dotted line.

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

A handwritten signature in blue ink, appearing to read 'Bernd Schell', positioned above a dotted line.

Bernd Schell  
Director Regulatory Affairs GSS

Validity date from: 19<sup>th</sup> January 2023

**EU Declaration of Conformity for Medical Devices**

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Document type for QSD: F

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**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