



Declaration of Conformity

Product Family Name: RUBY 7 HD

Basic UDI-DI: 0850018342RUBY7HDH8

Product Model(s): RUBY 7 HD / RUBY 7 HD+ / RUBY 7 HD No Storage / eMag 70 HD

Product Risk Classification: Class I

Directive(s)/Regulation(s): MDR (EU) 2017/745

Standard(s) Applied:

Standard(s)	Standard(s)
IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012 EN 60601-1:2006 + Cor. :2010 + A1:2013 IEC 60601-1-2:2014 / EN 60601-1-2:2015 Group 1 Class B	IEC 62133 IEC 62133-2:2017 EN 62133-2:2017 and UN38.3
IEC 60601-1-6:2010 + A1:2013 +A2 :2020 EN 60601-1-6:2010 + A1:2015	IEC 62366-1:2015 + COR1:2016 EN 62366-1:2015 + AC:2015
BS EN 12182:2012 EN ISO 14971:2019	UL 1642, 5 th Edition

Legal Manufacturer:

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I, the undersigned, hereby declare that this declaration is issued under the sole responsibility of the Manufacturer, and that the equipment specified herein conforms to the above Directive(s) and Regulation(s).

Name: Patrick Murphy

Title: Director of Engineering

Signature: [Handwritten Signature]

Date: 1-10-2022

Place of Issue: Florida, USA

Date Issued: 01-10-2022