



Declaration of Conformity

Product Family Name: RUBY XL HD

Basic UDI-DI: 0850018342RUBYXL6U

Product Model(s): RUBY XL HD / RUBY XL HD (B/W) / RUBY XL HD w/o Storage / eMag 50

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	UL 1642, 5 th Edition
EN ISO 14971:2019	

Legal Manufacturer:

Freedom Scientific
17757 US Highway 19 N, Suite 560
Clearwater, FL USA 33764
Telephone: 1-727-803-8000
eMail: info@vispero.com

Authorized Representative:

Optelec Nederland B.V.
Pesetastraat 5^a
2991 XT Barendrecht
The Netherlands

I, the undersigned, hereby declare that the equipment specified herein conforms to the above Directive(s) and Regulation(s).

Name: Patrick Murphy

Title: Dir. Hardware Engineering

Signature:

Date: 05-17-2021

Place of Issue: Clearwater FL USA

Date Issued: 04-30-2021