



Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
HeRO	HeRO symphony HeRO duet HeRO solo HeRO ES	
MANUFACTURER		
Name of company	Address	Representative
Medical Predictive Science Corporation (MPSC)	1233 Cedars Court Suite 201 Charlottesville, VA 22903	Raymond L. Schumin
AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
MedEnvoy Global B.V.	Prinses Margrietplantsoen 33 Suite 123 2595AM The Hague The Netherlands	+31.70.326.2148 EU-AR@medenvoyglobal.com
REGISTRATION INFORMATION		
Notified Body and ID #	CE certificate number	
NSAI 0050	252.861	
CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class II B Rule 10	Annex 2 of MDD 93/42/EEC Council Directive as amended by 2007/47/EC	EN ISO 13485:2016 EN ISO 14971:2019 EN 60601-1:2006/A1:2013 (IEC 60601-1:2005 3.1 Edition) EN 60601-1-2:2015 EN 60601-1-6:2010 EN 60601-1-8:2006 EN 62304:2006/AMD1:2015 EN 62366-1:2015 EN 15223-1:2016

MPSC declares that the above-mentioned products meet the provision of the Council Directive 93/42/EEC as amended by 2007/47/EC for Medical Devices and Directive 93/42/EEC as amended by 2007/47/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Raymond L. Schumin

TITLE: Director of Quality and Regulatory Affairs
DATE: 10/12/2023

SIGNATURE:


Ray Schumin