1 Purpose

This document provides the Declaration of Conformity to the RED Directive, 2014/53/EU, Annex II (Internal Production Control), for the ReActiv8 System.

2 Manufacturer

Mainstay Medical Limited,
Clonmel House,
Forster Way,
Swords, K67F2K3, Co. Dublin
Ireland

3 ReActiv8 Definition

The object of the declaration is the ReActiv8 System which includes the following:

Implantable Elements of the ReActiv8 System

- Model 5100 ReActiv8 Implantable Pulse Generator (“IPG”)
- Model 8000-45 ReActiv8 Percutaneous Lead, 45 cm length (“Leads”)
- Model 8000-65 ReActiv8 Percutaneous Lead, 65 cm length (“Leads”)
- Model 8145 ReActiv8 Percutaneous Stimulation Lead, 45 cm length (“Leads”)
- Model 8165 ReActiv8 Percutaneous Stimulation Lead, 65 cm length (“Leads”)

External Elements of the ReActiv8 System

- Model 4000 ReActiv8 Magnet (“Magnet”)
- Model 5500 ReActiv8 Torque Wrench (“Torque Wrench”)
- Model 6000 ReActiv8 Programmer Wand (“Wand”)
- Model 7000 ReActiv8 Activator
- ReActiv8 Version 1.0.1.6 Application Software (English)
- ReActiv8 Version 1.0.1.9 Application Software (Multilanguage)
- TUN1 Mainstay Tunneler

IPG Firmware
Version 1.11

Activator Firmware
Version 0.7

4 Applicable Directives

The following Directives are applicable to the ReActiv8.
Radio Equipment Directive 2014/53/EU, Annex II (Internal Production Control)

Standards Applied
Please see Attachment 1

Declaration of Conformity
I hereby declare that the above mentioned devices comply with the Essential Requirements and Provisions of the Radio Equipment Directive 2014/53/EU, Annex II (Internal Production Control)

Signed for and on behalf of Mainstay Medical:

Authorized Signatory:

Signature:	
Function:	Chief Operating Officer
Place of Issue:	Mainstay Medical Limited, Dublin, Ireland.

ATTACHMENT 1
Standards Applied

STANDARD or Regulation	COMPLIANCE (FULL OR PARTIAL)
Radio Equipment Directive 2014/53/EU	FULL
Draft* ETSI EN 301 489-1 V2.2.0 (2017-03), ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU	FULL
Draft* ETSI EN 301 489-31 V2.2.0 (2017-03), ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU	FULL
ETSI EN 302 195 V2.1.1 (2016-06), Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU	FULL

*These standards are at status “on approval” per http://www.etsi.org