

Declaration of Conformity

for DS7 Constant Current High Voltage Stimulators

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	DS7 Constant Current High Voltage Stimulators
Legal Manufacturer:	Digitimer Ltd, 37 Hydeway, Welwyn Garden City AL7 3BE UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	For use during neurological monitoring and assessment in a clinical environment
MDD Classification:	Class IIa
Notified Body:	SGS Belgium NV, SGS House, Nooderlaan 87, 2030 Antwerp, Belgium - Notified Body Number 1639
CE Certificate Reference:	GB19/964554
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Full Quality Assurance in accordance with Annex II of the Medical Device Directive

Name J P Cooper **Position** Technical Director

Signed  **Date** 01/03/2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
EN 60601-1:2006 + A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
EN 62366-1:2015	Medical devices-Part1: Application of usability engineering to medical devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code	UDI-DI
DS7A	DS7A Constant Current High Voltage Stimulator	35729	5060490360003
DS7AH	DS7AH Constant Current High Voltage Stimulator	35729	5060490360010
DS7AP	DS7AP Constant Current High Voltage Stimulator	35729	5060490360058

Version History

Version	Compiled by	Date	Description
6.0	KFJ	01/03/2021	Sixth issue