Declaration of Conformity for Accel-Heal

European Communities Council Directive 93/42/EEC as amended 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 Medical Device Directive 93/42/EEC provisions that apply to them and confirm that the CE Mark may be affixed.

General Product Name:	Accel-Heal
Legal Manufacturer:	Accel-Heal Technologies Limited Hever Business Centre, The Old Station, Hever, Kent TN8 7ER, UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Non-sterile, single-use electrical stimulation therapy for painful and hard-to-heal wounds.
MDD Classification:	Class IIa, in accordance with Rule 9 of Annex IX
Notified Body:	SGS Belgium NV (NB# 1639). SGS House, Noorderlaan 87, 2030 Antwerpen, Belgium
CE Certificate Reference:	GB19/964796
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Full Quality Assurance in accordance with Annex II of the Medical Device Directive

This declaration of conformity is issued under the sole responsibility of the manufacturer, Accel-Heal Technologies Limited.

Name Andrew Wildman **Position** Director

Signed  **Date** 16/09/2022

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 14971:2019	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

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
K560-6	Accel-Heal	35046
K560-1	Accel-Heal Solo	35046

Version History

Version	Compiled by	Date	Description
F	J. Wootten	18/05/21	First Issue (new template)
G	J. Wootten	16/09/2022	Add SGS Belgium NB# and address, addition of classification rule