Declaration of Conformity

for Greenlight 300

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:	Greenlight 300
Legal Manufacturer:	AC Cossor and Son (Surgical) Limited Greig House Block 1 Annickbank Innovation Campus Annick Road Irvine Scotland United Kingdom KA11 4LF
Variants:	As per Appendix II – Product Listing/Schedule
Intended Use:	Greenlight 300 is an electronic Sphygmomanometer used along with a stethoscope to measure systolic and diastolic blood pressure
MDD Classification:	Class II(a)
Notified Body:	Intertek Semco AB 0413
CE Certificate Reference:	41371237-03
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	EC Declaration of Conformity in accordance with Annex VII of the Medical Device Directive coupled with EC-Verification outlined in Annex IV

Name Hugh Templeton **Position** Quality & Technical Manger

Signed **Date** 15/04/2021

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

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
0701	Accoson Greenlight 300 Calibration Test Kit	16174
0702A	Accoson Greenlight 300 Sphygmomanometer	16174

Version History

Version	Compiled by	Date	Description
1.0	Hugh Templeton	10/11/2020	First issue.
1.1	Hugh Templeton	24/11/2020	Update to address & addition of NB #
1.2	Hugh Templeton	15/04/2021	Addition of Greenlight 300 Calibration Test Kit