EC Declaration of Conformity

Sky Medical Technology Ltd also trading as Firstkind Ltd

Hawk House, Peregrine Business Park, Gomm Road, High Wycombe, HP13 7DL

EC Declaration of Conformity to Medical Devices Directive 93/42/EEC (Annex II, excluding section 4) and Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Sky Medical Technology Ltd hereby declares that its portable, electro-stimulation devices

Medical Device Classification: IIa (Annex IX Rule 9)

Models: firefly™ T-2, geko™ T-2, geko™ T-3, geko™ W-3

EC Certificate Full Quality Assurance System Number: GB19/964606

Issued by:

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030
Antwerp
Belgium

-conform to the relevant provisions and essential requirements of the EC Council Directive 93/42/EEC dated 14 June 1993 and subsequent revisions, and in accordance with the provisions of Annex II excluding section 4 and is manufactured under an ISO 13485:2016 Quality Management System, certificate number GB12/87340, issued by SGS United Kingdom Ltd.

-conform to the requirements of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Sky Medical Technology Ltd confirms that its Notified Body is SGS Belgium NV (Notified Body number 1639) and that no other application has been lodged with another Notified Body for the same medical devices.

The EU Authorised Representative is:

Emergo Europe B.V.
Prinsessegracht 20
2514 AP The Hague,
The Netherlands

Appendix 1 - Applied Standards
Appendix 2 - List of Products

Signed by the Sky Medical Technology Ltd designated representatives:

Neil Buckley

Name: Neil Buckley Title: Head of Quality & Regulatory Affairs Date: Nov 25, 2021

Bernard J Ross
Bernard J Ross (Dec 1, 2021 15:07 GMT)

Name: Bernard Ross Title: CEO Date: Dec 1, 2021

Appendix 1
Applied Standards

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 (ISO 14971:2007)
EN 60601-1:2006/A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance IEC 60601-1:2012 reprint
EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2014
EN 60601-2-10:2015	Medical electrical equipment -- Part 2-10: Particular requirements for the safety of nerve and muscle stimulators IEC 60601-2-10:2012, *AMD1:2016
EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 60601-1-6:2007/AC:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 60601-1-6:2010
EN 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment IEC 60601-1-11: 2015
EN 62304:2006	Medical device software - software life-cycle processes IEC 62304:2006
IEC 60086-4:2007	Primary Batteries: Safety Standard for Lithium Batteries
IEC 60417-2:1998	Graphical symbols for use on equipment: Symbol originals
BS EN ISO 14644-1:1999	Cleanrooms and associated controlled environments: Classification of air cleanliness
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
BS EN 60529:1992 +A2: 2013	Degrees of protection provided by enclosures (IP code)
BS EN 62366-1:2015	Application of usability engineering to medical devices

Appendix 2
Full product list

Product Name	Product reference/SKU
firefly T-2	
firefly T-2(pouch, 2 x devices)	ST2RW02
firefly T-2(Wallet, 2 x devices)	ST2RW02-01
firefly T-2 (Wallet, 8 x devices)	ST2RW02-04
firefly T-2 (Carton, 50 x devices)	ST2RW02-25
geko T-2	
geko T-2 (pouch, 2 x devices)	MT2RW02
geko T-2 (pouch, 2 x devices)	MT2FE02
geko T-2 (2 x 25)	MT2RW25
geko T-2 (2 x 25)	MT2FE25
geko T-3	
geko T-3 (pouch, 2 x devices)	T3RW02
geko T-3 (2 x 25)	T3RW02-25
geko T-3 (pouch, 2 x devices)	T3EP02
geko T-3 (2 x 25)	T3EP02-25
geko T-3 (pouch, 2 x devices)	T3ME02
geko T-3 (2 x 25)	T3ME02-25
geko T-3 (pouch, 2 x devices)	T3FE02
geko T-3 (2 x 25)	T3FE02-25
geko T-3 (pouch, 2 x devices)	T3EA02
geko T-3 (2 x 25)	T3EA02-25
geko T-3 (pouch, 2 x devices)	T3BG02
geko T-3 (2 x 25)	T3BG02-25
geko W-3	
geko W-3 (pouch, 1 x devices)	W3RW01
geko W-3 (wallet, 7 x devices)	W3RW01-07
geko W-3 (pouch, 1 x devices)	W3FE01
geko W-3 (wallet, 7 x devices)	W3FE01-07