Outie Tool®

Nadine & Company LLC

DECLARATION OF CONFORMITY FOR OUTIE TOOLS

UK Medical Device Regulation, 2002 (as amended by UK MDR 2019)

Doc Number: DOC-02, Rev. 00

Manufacturer:	**UK- Responsible Person (UK-RP)**
Nadine & Co. LLC 10079 Pandora Drive La Mesa, CA 91941, USA T: 619-439-6311 E-mail- james@outietool.com https://www.outietool.com/	Certification Experts B.V. Amerlandseweg 7, 3621 ZC Breukelen, The Netherlands T: +31 (0) 850073210 E-mail- info@certification-experts.com

Product Name: Outie Tools

Model code: version 4

Available in different colour variations- Sky Blue, Neon Green, Hot Pink, Midnight and Pacific

Product Class and Rule: Class I, Rule 5

Technical Document: TD-02, Technical Document for Outie Tools

We declare under our sole responsibility that the distributed UKCA marked device, Outie Tools & its family of devices are in conformity with the "The Medical Device Regulation 2002 (as amended by UK MDR 2019)" of Part II of Schedule 2A of the UK Medical Device Regulations 2002 (Annex VII of MDD 93/42/EEC). Technical Document and technical details of products are at manufacturer's disposal. The device is in compliance with the Annex I (as modified by Part II of Schedule 2A to the UK MDR 2002), Essential Requirements Checklist of the regulation. The manufacturer is self-declaring the conformity of the device, Outie Tools to the listed harmonized standards which are applicable to them.

Reference	Title
EN ISO 13845:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971 :2012	Medical devices - Application of risk management to medical devices (ISO 14971 :2007, Corrected version 2007-10-01)
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
ISO 11737:2006/R:2011	Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Reference	Title
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10: 2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

Date: 21st June 2021

UK CA

Signed for and behalf of Nadine & Company LLC

Name of Signee: Nadine Saubers, President

Revision History

Rev	Date	Description	Revised by
00	21st June 2021	New Document	