



Declaration of Conformity

U-earth Biotech Ltd (Italian branch), in the person of Elisabetta Maggio, as agent

based in Milan Italy, via Bandello 16 - VAT number 10920970968 and CF 95209340108

on behalf of the manufacturer U-earth Biotech Ltd

based in London UK, 38 Craven Street WC2N 5NG - VAT N. GB311666618

declare

that the product: facial mask U-MASK MODEL 2

Model e code: U-MASKM2

Class: I

Manufacturing date: see label

Lot Number: see label

has been made in compliance with the following directives and standards:

- Regulation (EU) no. 745/2017 Regulation relating to medical devices, which amends directive 2001/83 / EC, Regulation (EC) no. 178/2002 and Regulation (EC) no. 1223/2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC
- Standard IEC 61882: 2016 Risk analysis method according to the HAZOP method
- CEI EN 61511-1 Functional safety - Safety instrumented systems for the process industry sector - Part 1: Framework, definitions, system, hardware and application programming requirements
- UNI CEI EN ISO 15223-1: 2017 Symbols to be used in the medical device labels, in the labeling and in the information that must be provided - Part 1: General requirements
- UNI CEI EN 1041: 2009 Information provided by the Manufacturer with medical devices
- UNI CEI EN 14971: 2012 Application of risk management to medical devices
- Dir. 93/42 / CEE, D.L. 02/24/97 nr. 46, Legislative Decree 25/02/98 nr. 95 Council Directive concerning medical devices - Implementation of Directive 93/42 / EEC concerning medical devices. Changes to the Legislative Decree 24 February 1997 nr. 46 (which will coexist with the new Regulation until 2020)
- Dir. 2007/47 / CEE D.L. 1/25/10 nr. 37 Council Directive concerning medical devices Implementation of Directive 93/42 / EEC concerning medical devices. (which will coexist with the new Regulation until 2020)
- Regulation (EU) no. 1007/2011 relating to the names of textile fibers and to the labeling and marking of the fibrous composition of textile products
- UNI EN 14683:2019 Title: facial masks as medical device - requirements and test methods
- Test on breathability, biocompatibility and microbial cleanliness tests ISO 11737. BFE test with alternative method as required by the standard.
- ISO 10993-1:2009
- Test on EN ISO20743; UNI EN ISO 20645:2005: ASTM E 2149-01; UNI 8986
- Complete toxicologic test

It therefore complies with the directives and regulations in force.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Place: Milan (Italy)

signature:

Date: January 27th, 2021

Elisabetta Maggio

Rev. 01



Via Lauro, 95 Cadoneghe Padova Italy

Consulenti e Periti per: Guardia di Finanza, Tributaria, Autorità Doganali, Carabinieri, Polizia di Stato, Unioncamere, Tribunali.

The correct preparation of the technical file, as well as the documents prepared by C&C s.a.s., have been verified by Eng. Renato Carraro.