

EU Declaration of Conformity

We, **Invention Works B.V.**, declare under our sole responsibility that the home skin treatment products

Model Name: ***Silk'n Infinity***
Model Number: ***H3101***
Article Number: ***INFIPE3R001***

with the included component RN4020 (Bluetooth 4.1 Low Energy Module)

Fully in conformity with the essential requirements of Council Directives:

*Medical Device Directive MDD 93/42/EEC
Radio Equipment Directive 2014/53/EU
Restriction of Hazardous Substances Directive 2015/863 amending Annex II to Directive 2011/65/EU
REACH Regulation EC No. 1907/2006*

This declaration is based on the full compliance of the product (s) with the following standards:

IEC 60601-1:2005 (Ed.3.0) + CORR.1:2006+CORR.2:2007+A1:2012	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-2: 2014 Ed. 4.0	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 300 328 V2.2.2	Radio spectrum
EN 301 489-1 V2.2.3	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for Electromagnetic Compatibility
EN 301 489-17 V3.2.4	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for Electromagnetic Compatibility

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Signed:

Oscar Middendorp
General Manager
Europe

May 18, 2022

