YouMedical B.V. – also doing business as Trimb Healthcare **–**
Barbara Strozzilaan 201, 1083 HN Amsterdam / The Netherlands

ID Nr: DHF-7.1.2_v19.0_2022-08-04

DECLARATION OF CONFORMITY

We, YouMedical B.V., also doing business as Trimb Healthcare, hereby declare that the distributed CE marked products, specified below, first manufactured on 23 December 2019, with batch number 95211, are covered by the "CE Marking of Conformity Certificate" Reference number: 216219CE02 issued on 20 January 2020 by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and conform to the required technical documentation, in accordance with Annex VII of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices and all harmonized standards which are applicable to the object, as published in the Official Journal of the European Communities.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex V of the EC-Directive. The conformity of the production quality assurance set out in Annex V, is described in the said CE Marking of Conformity Certificate, issued and delivered by Dekra.

This declaration of conformity is supported by the Quality System certification based on the harmonized standards ISO 13485, Quality System Certificate for YouMedical B.V. with reference number: 2161219, first issued on 8 July 2013, and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344.

Article(s) marked with the * in below table is/are new trade name(s) for the existing product range therefore considered non-significant changes according to MDR Article 120.

All products below are monitored according to PMS requirements of MDR 2017/745.

This Declaration of Conformity covers products as specified below and is valid for all products concerned bearing the CE marking.

Stockholm, 04 August 2022

Karo Pharma
Mahsa Aspsäter
Head of Regulatory Affairs

Product name	First batch	Date
CWFO Advanced 15APP / Wortie Cool, US	95211	2019-12-23

Product Range

Article Name	Article Number
Wortie Cool/ Wortie Freeze50ml, SE/NO	**1000119**
Wortie Advanced/ Wortie Freeze Plus 50ml, SE/NO	**1000118**
Wortie Advanced, PL	**1000917**
Wortie Advance/ Wortie Freeze Plus 50ml, UK	**1000116**
Wortie Cool/ Wortie Freeze 50ml, UK	**1000117**
Wortie Cool/ Wortie Freeze50ml, NL	**1000174**
Wortie Advanced/ Wortie Freeze Plus50ml, NL	**1000175**
CWFO Advanced 15APP / Wortie Cool, US	**1000176**
CWFO Advanced/Wortie Cool, CA	**1000177**
CW COMPLT WART KIT 12 / Wortie Advanced, US	**1000178**
Wortie , PL	**1000192**
Wortie Cool, ES	**1000193**
Wortie Skin Tag (Expert 123), FR	**1000194**
Wortie Advanced FI	**1000198**
Wortie Cool/ Expert 123, FR	**1000200**
Wortie Cool KW	**1000201**
Wortie Cool RO	**1000204**
Wortie Skin Tag ES	**1000208**
Wortie Skin Tag MENA	**1000209**
Wortie Advanced 50ml, MENA	**1000210**
Wortie Cool, CH	**1000215**
Wortie DE / Wortie gegen Hand- und Fußwarzen/ Wortie Freeze 50ml OP1	**1000216**
Wortie Cool, Baltics	**1000221**
Wortie Advanced Baltics EE	**1000222**
Wortie , IT	**1000224**
Wortie Advanced, FR / Expert 123 Intensive	**1000226**
Wortie Cool, HU	**1000227**
Wortie Cool MENA	**1000228**
Wortie Skin Tag, DE / Wortie spezial gegen Stielwarzen 50ml OP1	**1000229**
Wortie Cool, AT	**1000230**
Wortie Skin Tag, MY	**1000245**
Wortie Advanced, MY	**1000246**

Wortie Cool IL	**1000437**
Bevitamed/Wortie Cool FI	**1000452**
Wortie Advanced, DE / Wortie Intens / Wortie Freeze Plus 50ml OP1	**1000733**
Wortie Cool, BE	**1000751**
Wortie Advanced, BE	**1000752**
Wortie Skin Tag, Baltics	**1000869**
Wartie Cool, AU	**1000219**
Wartie Advanced, AU	**1000220**
Wartie Cool, CL	**1001006**
WORTIE LIQUID NL - 5ml	**1000441 (*)**
WORTIE SKIN TAG NL	**WS001 NL (*)**