

EC DECLARATION OF CONFORMITY

We,

IDCP BV
Manuscriptstraat 12-14
1321 NN Almere
The Netherlands
SRN: NL-MF-000000755

hereby declare under our sole responsibility that the CE-marked products to which this declaration relates,

TrichoScope Basic (type number MEDL3H, Basic UDI-DI 87202991629MEDL3HG2) TrichoScope Polarizer (type number MEDL4HM, Basic UDI-DI 87202991629MEDL4HMTN) and

TrichoScope Polarizer HR (type number MEDL7HM, Basic UDI-DI 87202991629MEDL7HMU5)

having the intended purpose: The TrichoScope is intended to make images of hair and scalp for hair and scalp diagnosis,

and have been classified as Class I, according to Annex VIII, Rule number 10, and the related software is classified as Class I according to Rule 11,

and are in conformity with the General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,

and are in conformity with the standards EN 1041:2008 and EN ISO 15223-1:2016,

and are in conformity with 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.

Signature:

Naarden, The Netherlands Date: 9 - 2 - 2021

Name: Jan Boers

Function: Managing Director