

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,

DermaScope Polarizer 200x (type number MEDL4DM, Basic UDI-DI 87202991629MEDL4DMTA),

DermaScope Polarizer HR 200x (type number MEDL7DM, Basic UDI-DI 87202991629MEDL7DMTR),

DermaScope Polarizer (type number MEDL4DW, Basic UDI-DI 87202991629MEDL4DWTW)

and

DermaScope Polarizer HR (type number MEDL7DW, Basic UDI-DI 87202991629MEDL7DWUD)

having the intended purpose: The DermaScope is intended to make images of spots of the intact skin as part of a dermatological 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: S - 2 · 20 2 (

Name: Jan Boers

Function: Managing Director