IDCP

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,

EarScope Pro (type number MEDL4E, Basic UDI-DI 87202991629MEDL4EFX)
EarScope Basic (type number MEDL3E, Basic UDI-DI 87202991629MEDL3EFU)
and
EarScope Pneumatic (type number MEDL4EP, Basic UDI-DI 87202991629MEDL4EPTK)

having the intended purpose: The EarScope is intended to make images of the inner ear as part of an ear diagnosis,

and have been classified as Class I, according to Annex VIII, Rule number 10, and the related DinoCapture software is classified as Class I, because the software drives the EarScope or influences the use of EarScope and consequently shall fall within the same class as the EarScope,

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