

EC DECLARATION OF CONFORMITY

We,

IDCP BV Energiestraat 23A 1411 AR Naarden

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

CapillaryScope 500 (type number MEDL4N5)
CapillaryScope Pro 200 (type number MEDL4N Pro)
and
CapillaryScope Pro 500 (type number MEDL4N5 Pro)

have been classified as Class I, according to Annex IX, rule number 12,

and are in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC and are in conformity with the relevant harmonized 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,

and are subject to the procedure set out in Annex VII of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

Signature

Date: 19-7-2018

Name: Jan Boers

Function: Managing Director















