Declaration of Conformity

Product identification		
Product name	**Description**	**Device classification**
VISUSCOUT 100	Mobile fundus camera with ophthalmoscopic lens	IIa, rule 10
VISUSCOUT 100 charging station	Charging cradle, accessory	Medical device accessory

Manufactured for	
Name of company	**Address**
Carl Zeiss Meditec AG	Goeschwitzer-Str. 51-52, 07745 Jena, Germany

Manufacturer	
Name of company	**Address**
Optomed Oy	Yrttipellontie 1, FI-90230 Oulu, Finland

Registration information	
Notified Body and ID number	**CE Certificate number**
SGS 0598	FI16/07004

Conformity assessment		
Device classification	**Route to compliance**	**Standards applied**
IIa, rule 10	Annex II, section 3 of MDD 93/42/EEC	ISO 13485:2016 IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + A1:2012 IEC 60601-1-2:2014, EN 55011 Class B IEC 60601-1-4:1996 + A1:1999 IEC 60601-1-6:2014 EN 50581:2012 EN 62366:2007 + A1:2014 IEC 62304:2006 + A1:2015 EN ISO 14971:2012 EN ISO 15004-1:2006 EN ISO 15004-2:2007 ISO 10940:2009 EN 62471:2006 ISO 14155:2011 ISO 10993-5:2009 ISO 10993-10:2009 IEC 60601-1-9:2007 +A1:2013

Medical device accessory	N/A	Accessory tested as part of VISUSCOUT 100

We, Optomed Oy, declare under our sole responsibility that the above mentioned products meet the provisions of Council Directive 93/42/EEC for Medical devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

Additionally, we Optomed Oy, declare under our sole responsibility that the above mentioned products are in conformity with directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

COMPANY REPRESENTATIVE: Seppo Kopsala
TITLE: CEO
SIGNATURE: 

DATE: 2019 10 18

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