Declaration of Conformity

PRODUCT IDENTIFICATION	
Product Name	**Model Number**
Reichert® 7CR Auto Tonometer + Corneal Response Technology®	**16060**

MANUFACTURER		
Name of Company	**Address**	**Representative**
Reichert, Inc.	3362 Walden Avenue, Suite 100 Depew, New York 14043 USA	Elizabeth Schultz

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**Telephone/Email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	Tel: (31) (0) 70 345-8570 Email: EmergoEurope@ul.com

REGISTRATION INFORMATION	
Notified Body and ID Number	**CE Certificate Number**
SGS Belgium NV - 1639 **SGS House** **Nooderlann 87** **2030 Antwerp** **Belgium**	**US19/819943482**

CONFORMITY ASSESSMENT			
Device Classification	**Route to Compliance**	**Quality Standards Applied**	
Class IIa Rule 10	Annex II of MDD 93/42/EEC Council Directive	IEC 60601-1:2012 IEC 60601-1-2:2014 IEC 62304:2015	EN ISO 14971:2012 IEC 62366:2007 +A1:2014 IEC 60601-1-6:2010 +A1:2013

Reichert, Inc. declares that this product meets the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

Reichert, Inc. declares that this product meets the requirements of the Restriction of Hazardous Substances (RoHS) Directive, RoHs (EU) 2015/863.

Reichert, Inc. designs and manufactures all products under quality assurance processes that have been certified to meet EN ISO 13485:2016 requirements (SGS Certificate US01/54027).

COMPANY REPRESENTATIVE: Elizabeth Schultz

TITLE: Regulatory Manager

DATE: 23-06-2021

SIGNATURE:

Digitally signed by Bas Dumitru
Date: 2024.10.24 17:32:41 EEST
Reason: MoldSign Signature
Location: Moldova
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