



Declaration of Conformity

Product Family Name: COMPACT 10

Basic UDI-DI: 0850017300CP10KX

Product Model(s): Compact 10 HD Speech / Compact 10 HD

Product Risk Classification: Class I

Directive(s)/Regulation(s): MDR (EU) 2017/745

Standard(s) Applied:

MDR (EU) 2017/745	2014/53/EU RED
IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012 EN 60601-1:2006 + Cor. :2010 + A1:2013 IEC 60601-1-2:2014 / EN 60601-1-2:2015 Group 1 Class B	ESTI EN 301 489-1 V1.9.2 :2011-09
IEC 60601-1-6:2010 + A1:2013 +A2 :2020 EN 60601-1-6:2010 + A1:2015	
EN ISO 14971:2019	ESTI EN 301 489-3 V1.6.1 :2013-08
BS EN 12182:2012	ESTI EN 301 489-1 V2.1.1 :2017-02
IEC 62366-1:2015 + COR1:2016 EN 62366-1:2015 + AC:2015	ESTI EN 301 489-17 V3.1.1:2017-02
IEC 62133 IEC 62133-2:2017 EN 62133-2:2017 and UN38.3	ESTI EN 300 328 V2.1.1 :2016-11
UL 1642, 5 th Edition	

Legal Manufacturer:

Optelec Nederland B.V.
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Authorized Representative:

N/A

I, the undersigned, hereby declare that the equipment specified herein conforms to the above Directive(s) and Regulation(s).

Name: B.J.M.Kofflard

Title: Managing Director

Signature: 

Date: 17th of May 2021

Place of Issue: Barendrecht

Date Issued: 04-30-2021