

EU declaration of conformity

We, the company

Dr. Jean Bausch GmbH & Co. KG
Oskar-Schindler-Straße 4
50769 Cologne
Germany

declare as manufacturer, SRN: DE-MF-000005577 in sole responsibility, that the products listed from page 2 onwards of the

Product group: 10.1 OccluSense®
Basic UDI-DI: ++E21010x1xOccluSense98

meet the applicable requirements of Regulation (EU) 2017/745 on medical devices and the subsequent regulations and standards:

Regulation (EU) 2017/745
Directive 2014/53/EU
EN 10993-1:2020
EN 14971:2019
EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015
EN 60601-1-6:2010 + A1:2015
EN 62304:2006 + A1:2015
EN 62366:2015 + AC:2015 + A1:2020

The technical documentation proving compliance with the requirements of the above-mentioned regulations and standards is documented in the Development File and Medical Devices File parts of the technical file and is available to the National Competent Authorities.

This declaration of conformity is valid from: 2021-10-25.



Signed by: André Bausch
Authority: General Manager of Dr. Jean Bausch GmbH & Co. KG

Date of signature: 2021-10-25
Place of signature: Cologne - Germany

[illegible]