

General Declaration of Conformity for Custom-made Devices

April 29, 2021

Name of Manufacturer: OraMetrix

Manufacturer Address: 2350 Campbell Creek Blvd. Suite 400, Richardson, Texas 75082, U.S.A.

Manufacturer's Authorized Representative: OraMetrix GmbH

Manufacturer's Authorized Representative Address: Rungestraße 19, 10179 Berlin, Germany

Product Identification: Custom-made aligner, aligner attachment tray, retainer, wire and IDB tray.

These devices are intended for exclusive use by a particular patient and are placed on the market according to the specific characteristics of the device indicated by the doctor's prescription. See patient and product information on labeling. These custom-made devices conform with the General Safety and Performance Requirements set out in Annex I of Regulation (EU) 2017/745 and Annex XIII Procedure for Custom-made Devices of Regulation (EU) 2017/745.

This declaration is to confirm our compliance with the Regulation (EU) 2017/745 requirements and will not be included with each custom-made device shipment as the labeling fulfills the statement requirements of Annex XIII of the Regulations.

Richardson, TX 29 APR 2021

Place and Date



Scott Lurgio
Director of QA & RA
Dentsply Sirona Orthodontics Inc.