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# EU Declaration of Conformity

We: Water Pik, Inc.
1730 East Prospect Road
Fort Collins, CO 80553-0001
USA

EC Representative
Sofibel SAS
92686 Levallois-Perret Cedex-France

declare under our sole responsibility, using the conformity assessment route through Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices Annex VIII, Rule 5, that the

- **Tra-Tens Impression Trays**
  - Upper (13451-000, 13452-000, 13453-000)
  - Lower (13454-000, 13455-000, 13456-000)
  - Anterior (13457-000)
  - Bilateral (13458-000, 13459-000)
- **Master Tray Impression Trays**
  - Upper (011211-000, 011213-000, 011215-000)
  - Upper (011201-500, 011203-500, 011205-500)
  - Lower (011212-000, 011214-000, 011216-000)
  - Lower (011202-500, 011204-500, 011206-500)
  - Partial (011217-000, 011218-000, 011207-500, 011208-500)
  - Anterior (011219-000, 011209-500)
- **Sani-Trays Dual Arch Impression Trays**
  - Anterior (20000537)
  - Posterior (20000538)
  - Sideless Posterior (20000540)
  - Quadrant (20000539)
- **Sani-Trays Impression Trays**
  - Upper, Perforated (011511-012, 011513-012. 011515-012)
  - Lower, Perforated (011512-012, 011514-012, 011516-012)
  - Partial, Non-perforated (011517-012, 011518-012)
  - Anterior, Non-perforated (011519-012)
  - Upper, Non-perforated (011521-012, 011523-012, 011525-012)
  - Lower, Non-perforated (011522-012, 011524-012, 011526-012)

classified as **Class I** meet the general safety and performance requirements and are in conformity with the Regulation listed below using the relevant sections of the Regulation and other normative documents:

**Regulation:**

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

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**Conformity Route:**

In accordance with Section 7 of Article 52 of the medical device regulation, the chosen conformity assessment procedure is declaration of conformity by issuing this EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III.

**Standards:**

- BS EN ISO 13485:2016 - Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- BS EN ISO 14971: 2012 - Medical Devices - Application of Risk Management to Medical Devices
- ISO 10993-1:2018 - Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process
- BS EN ISO 15223-1:2016 - Medical Devices - Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied - Part 1: General Requirements
- BS EN 1041:2008 + A1:2013 - Information Supplied by the Manufacturer of Medical Devices
- BS EN 1641:2009 - Dentistry - Medical Devices for Dentistry - Materials

Date CE mark was affixed (Master Tray®, Sani-Trays®, Sani-Trays® Dual Arch, and Tra-Tens® Impression Trays): **June 1996**

**Date** : 3 Sep 2020

**Signature** :

**Name** : Jeffrey M. Dornoff

**Title** : Senior Manager, Regulatory & Quality Systems

Supersedes: 19-September-2019
End Date: NA