



UK Declaration of Conformity

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

UK Responsible Person
Church & Dwight UK Limited
Wear Bay Road
Folkestone
Kent CT19 6PG
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declare under our sole responsibility, using the conformity assessment route, through Medical Devices Regulations (UK) 2002, Medical Devices (Amendment, EU Exit) Regulations 2020, and The Council of the European Communities Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices (as amended) Annex IX, Rule 5, that the

Product Description	Product ID	UDI-DI
Kelly's Z.O.E. Impression Paste	011350-000	D6860113503

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

Regulation:

Medical Devices Regulations (UK) 2002 and Medical Devices (Amendment, EU Exit) Regulations 2020.

Conformity Route:

In accordance with Section 5 of Article 11 of Council Directive 93/42/EEC (as amended), the chosen conformity assessment procedure is declaration of conformity by issuing this declaration of conformity after drawing up the technical documentation set out in Annex VII.

Standards:

- BS EN ISO 13485:2016 + A11:2021 - Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- BS EN ISO 15223-1:2021 – Medical Devices - Symbols to be Used with Information to be Supplied by the Manufacturer - Part 1: General Requirements
- BS EN ISO 20417:2021 – Medical Devices - Information to be Supplied by the Manufacturer
- BS EN 1641:2009 – Dentistry - Medical Devices for Dentistry - Materials
- BS EN ISO 14971: 2019 + A11:2021 - Medical Devices - Application of Risk Management to Medical Devices
- BS EN ISO 10993-1:2020 – Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process



Date UKCA mark affixed: **June 2022**

Date : 10-Jun-2022

DocuSigned by:
Jeffrey M. Dornoff
 Signer Name: Jeffrey M. Dornoff
Signing Reason: I approve this document
Signing Time: 10-Jun-2022 | 2:13:39 PM EDT
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Signature :
Name : Jeffrey M. Dornoff
Title : Senior Manager, Regulatory & Quality Systems

Supersedes: NA
End Date: NA