

90767-061 Rev. E

DECLARATION OF CONFORMITY

Product: BioSonic® UC150 Ultrasonic Cleaner

Models: BioSonic UC150

Basic UDI-DI: ++D661043KK

Classification: Class I [(EU) 2017/745 Annex VIII, Rule 13]

Legal Manufacturer: Coltene/Whaledent, Inc.
235 Ascot Parkway
Cuyahoga Falls, OH, USA
SRN: US-MF-000015761

European Representative: Coltene/Whaledent GmbH + Co. KG
Raiffeisenstrasse 30
89129 Langenau Germany
SRN: DE-AR-000005719

We herewith declare that the above-mentioned products meet the provisions of the following legislation(s) and that Coltene/Whaledent, Inc. has exclusive responsibility for the content of this Declaration of Conformity. All supporting documentation is retained at the manufacturer's premises.

General Applicable Legislation:

Medical Device Regulations: Regulation (EU) 2017/745 of April 2017 on medical devices (MDR 2017/745, Annex 52).

Standards and Common Specifications:

EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 62366:2008, IEC 61010-1:2010 (2016), IEC 61010-2-020:2019, IEC 60601-1-2:2015, AN/NZS 3000.1.1:2005, EN ISO 15223-1:2016, EN ISO 62304:2006

Notify Body: DEKRA Certification B.V.
Meander 1051
6825 MJ Arnhem

Certificate: N/A

Date of Effectiveness of Product Under this Declaration: May 26, 2021

Place: Cuyahoga Falls, OH, USA

Signature:  _____

Date: 11/04/2021 _____

Name & Title of Management Representative and PRRC: Tricia Cregger, Director of Regulatory/R&D

<u>Part Number</u>	<u>MDR Class</u>	<u>Description of Finished Product</u>	<u>Date CE Mark Affixed</u>
60021988	I	UC150 Cleaner Unit Euro Plug Type F	2019
60021989	I	UC150 Cleaner Unit UK Plug Type G	2017
60022040	I	Cassette Basket	2017
60022041	I	Beaker Holder	2018
60022042	I	Accessory Kit	2018
UC53	I	600mL Beaker with cover and Positioning Ring	2005