CERTIFICATE

Number: 3800582

The management system of:

Coltene/Whaledent, Inc.

235 Ascot Parkway
Cuyahoga Falls, OH 44223
United States Of America

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:
The design and development, manufacture, and distribution of Abrasive Disks, Dental Burs, Dental Handpiece, Dental Instrument Handle, Diamond Instruments, Electrosurgical Unit, Electrosurgical Electrodes, Endodontic Instruments, Endodontic Pulp Canal Files, Endodontic Root Canal Preparer, Impression Trays, Intraoral Dental Wax, Intraoral Dental Drill, Irrigation Syringe, Manual Instruments, Materials for Fabricating Prosthodontic Appliances, Periodontal Instruments, Pulp Tester, Retentive and Splinting Pins, Root Apex Locator, Root Canal Post, Rubber Dam, Rubber Dam Clamp, Rubber Dam Dental Punch, Rubber Dam Wedjet Stabilizing Cord, Rubber Dam Forceps, Rubber Dam Frame, Ultrasonic Scaler and Polisher, Ultrasonic Scaler and Polisher Tips, Ultraviolet Activator for Polymerization, Ultrasonic Cleaners and solutions for the area of Dentistry.

Service of Dental Handpieces, Electrosurgical Units, Endodontic Instruments, Root Apex Locator, Ultrasonic Scaler and Polisher, Ultraviolet Activator for Polymerization, Orthodontic Instruments, Ultrasonic Cleaners, Autoclave Sterilizers, Dental Instrument Washers, and Dry Heat Sterilizers for the area of Dentistry.

Certificate expiry date: 18 September 2027
Certificate effective date: 18 September 2024
Certified since: 10 October 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Certification Manager

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