



CERTIFICATE

EC Certificate No. 1434-MDD-233/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Rolence Enterprise Inc.

**No.18-3, Lane 231, Pu Chung Rd., Chugli,
Taoyuan 32083, Taiwan**

for the design, manufacture and final inspection of

medical devices, class IIa

**Ultrasonic scalers for areas of operative dentistry, and
portable dental X-ray systems**

List of devices covered by this certificate is given in the Annex no. 1


complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 25.04.2019 to 17.03.2021

The date of issue of the Certificate: 25.04.2019



Application No: 701/2019
Module H


mgr Anna Wyroba
Vice-President



Certificate No. **1434-MDD-233/2019**
Issued under the Contract No. **MD-84/2019**
Bears the PCBC hologram
Warszawa, 25/04/2019




ANNEX NO. 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-MDD-233/2019

The product detailed below are covered under the scope of this certificate:

Product Family	Product Sub-Group	Model/Type
Ultrasonic Scaler 'ELITEDENT'	MS Series	MS-1
		MS-1-Dual
		MS-10
		MS-10B
		MS-30
		MS-50
	PS Series	PS-1
		PS-1 Dual
		PS-25
		PS-25B
		PS-30




mgr Anna Wyroba
Vice-President



Annex no. 1 to certificate No. **1434-MDD-233/2019**
Issued under the Contract No. **MD-84/2019**
Bears the PCBC hologram.
Warsaw, 25/04/2019



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**Ultrasonic scalers for areas of operative dentistry, and
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Product Family: Portable X-Ray, Model/Type: XR-01

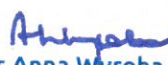
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Warszawa, 25/04/2019