



# CERTIFICATE

**EC Certificate No. 1434-MDD-136/2021**  
**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 Road, Chungli  
Taoyuan  
32083 TAIWAN, R.O.C.**

for the design, manufacture and final inspection of medical devices, class: **Class IIb**

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

*The list of medical devices covered by this certificate is provided in the Annex 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 18.03.2021 to 27.05.2024

The date of issue of the Certificate: 18.03.2021

The date of the first issue of the Certificate: 25.04.2019



Issued under the Contract No. MD-18/2021  
Application No: 507/2021  
Certificate bears the qualified signature.  
Warsaw, 18/03/2021  
Module H2/3/4/5  
FBM-26-E\_9

Anna  
Małgorzata  
Wyroba  
Vice-President

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.03.18  
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**ANNEX 1 TO THE CERTIFICATE**  
**VALID ONLY WITH CERTIFICATE**  
**No 1434-MDD-136/2021**

*List of medical devices covered by the certificate:*

<b>Product Family</b>	<b>Product Sub-Group</b>	<b>Model/Type</b>
Portable X-Ray	Portable X-Ray	XR-01
	Intraoral Digital X-Ray Sensor	RXS 1000



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