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

CE 1434

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
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.03.18 14:36:25 +01'00'
Vice-President

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-136/2021

List of medical devices covered by the certificate:

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

CE 1434

Issued under the Contract No. MD-18/2021
Application No: 507/2021
Certificate bears the qualified signature.
Warsaw, 18/03/2021

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.03.18 14:35:52 +01'00'
Vice-President

By Royal Charter

Supplementary information to AR120 815173

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

Rolence Enterprise, Inc.
No. 18-3, Lane 231, Pu Chung Road, Chungli
Taoyuan
32083, TAIWAN, R.O.C.

Date: 10 September 2024

Changes Approved:

Date	Reference Number	Action
10 September 2024	30248429	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of device Portable X-ray System and Intraoral Digital X-ray sensor. Original NB Certificate Number: 1434-MDD-136/2021

Inspiring trust for a more resilient world.

10 September 2024

Rolence Enterprise, Inc.
No. 18-3, Lane 231
Pu Chung Road
Chungli
Taoyuan
32083
Taiwan

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	**BSI Reference Number**	**Directive and Annex**	**Reference Number**	**Changes approved**
1434-MDD-136/2021	AR120 815173	93/42/EEC Annex II excluding Section 4	30248429	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of device Portable X-ray System and Intraoral Digital X-ray sensor. Original NB Certificate Number: 1434-MDD-136/2021

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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