EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Unident AB

Västerhavsvägen 2, SE-311 42 Falkenberg, Sweden

Manufacturer SRN: SE-MF-000004887

Scope:

Dental Imaging Software

Certificate Number:
28620145488

Revision:
00

Initial Certification Date:
23 March 2023

Certificate Decision Date:
23 March 2023

Certificate Issue Date:
23 March 2023

Certificate Expiry Date:
16 December 2027

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00170-01 Unident AB Onepix**
Audit Report Reference	**Stage 1 audit ACTY-2022-530489**
	Stage 2 audit ACTY-2022-530490
	Special Visit ACTY-2023-632624

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620145488

Revision:
00

Initial Certification Date:
23 March 2023

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MDR – Decision Report

Certificate No: 28620145488
Date: 23 March 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Unident AB
Attn: Maria Delin
Västerhavsvägen 2
SE-311 42 Falkenberg
Sweden

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.
Expiry date on MDR certificate is set to be aligned with client´s audit cycle for ISO 13485:2016 certificate.

Activity

Audit Type	Location	Auditor Name	Audit Date
Stage 1 ACTY-2022-530489	Falkenberg	Helen Attmarsson Rydén	8 – 9 Sept 2022
Stage 2 ACTY-2022-530490	Falkenberg	Helen Attmarsson Rydén	15 – 17 Nov 2022
Special Visit ACTY-2023-632624	Remote	Helen Attmarsson Rydén	2 March 2023

Technical Documentation Report	Assessor Name	Assessment Date
Final TDAR_Unident_TD00170-01_2023-02-15	Vageesha Singh	31 Jan 2023
Final CEAR_Unident_TD00170-01_2023-02-15	Vageesha Singh	31 Jan 2023

Scope of assessment

Dental Imaging Software, Class IIa

Result

4 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.

All non-conformities noted during the technical documentation assessment have been closed.

Certificate Valid from

23 March 2023

Conclusions/Decisions

Referring to the above, a Certificate of Conformance with the Medical Device Regulation 2017/745, Annex IX will be issued. The Certificate is valid for products specified in the “MDR – Product List”.

Follow-up assessments

Follow-up assessments are going to be performed once per year.

Appeals

Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR

Brian Mather
Certification Authority (Audit and TD Assessment)

PRODUCT LIST FOR CERTIFICATE

Issued to: Unident AB

Certificate number: 28620145488

Certificate valid from: 2023-03-23

Product List Issue Date:
23 March 2023

Product	Classification and EMDN	Intended use[1]	Date Added
Dental Imaging Software			
Basic UDI-DI: 735011864OPXK8			
OPX001 - Onepix	Class IIa Z110603		2023-03-23

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB, Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.