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.

Medlab Media Group, MMG

C/ Pollensa, number 6 Edif ECU 2, 2nd floor, Las Rozas de Madrid 28290 Spain

Manufacturer SRN: To be confirmed

Scope:

Computed Tomography Software Dental

Certificate Number:
28620156616

Revision:
00

Initial Certification Date:
13 September 2023

Certificate Decision Date:
13 September 2023

Certificate Issue Date:
13 September 2023

Certificate Expiry Date:
12 September 2028

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	**TD00119-01 Medlab Media Group, MMG Dentomo**
Audit Report Reference	**Stage 1 audit ACTY-2021-498771**
	Stage 2 audit ACTY-2021-501444
	Stage 2 Repeat ACTY-2023-645184
	Special Visit ACTY-2023-076030

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620156616

Revision:
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MDR – Decision Report

Certificate No: 28620156616
Date: 13 September 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Medlab Media Group, MMG
Attn: Daniel Guillermo Langton
C/ Pollensa, number 6 Edif ECU 2, 2nd floor
Las Rozas de Madrid 28290
Spain

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.

Activity

Audit Type	Location	Auditor Name	Audit Date
Stage 1 ACTY-2021-498771	Madrid	Helen Attmarsson Rydén	10 – 12 May 2022
Stage 2 ACTY-2021-501444	Madrid	Helen Attmarsson Rydén, Damon Harley, Dawn Chivers	28 – 29 June 2022
Stage 2 Repeat ACTY-2023-645184	Madrid	Dawn Chivers, Belén de Rábago, Reza Kharraziha	12 – 13 April 2023
Special Visit ACTY-2023-076030	Madrid	Dawn Chivers	13 July 2023

Technical Documentation Report	Assessor Name	Assessment Date
Final TDAR_Medlab Media Group_TD00119-02_2023-08-30	Vageesha Singh, Sharmila Gardner	30 August 2023
Final CEAR_Medlab Media Group_TD00119-02_2023-08-30	Vageesha Singh, Sharmila Gardner	30 August 2023
TD Request for Additional Information_Medlab Media Group_TD00119-01_2022-07-07_Review R1 response_2022-09-23	Vageesha Singh, Sharmila Gardner	30 August 2023
F104-3-MED-MDR Technical Documentation Assessment Non-Conformities_2023-08-30	Vageesha Singh, Sharmila Gardner	30 August 2023

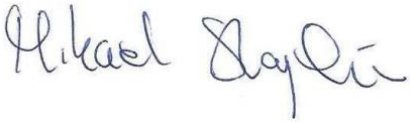
Scope of assessment

Computed Tomography Software Dental, Class IIa

Result	14 minor and 6 major non conformities were noted during the audit. The major non conformities was successfully closed out at the special visit. Presented corrective action plan for the minor non conformity has been examined and approved by us. All non-conformities noted during the technical documentation assessment have been closed.
Certificate Valid from	13 September 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 (TD Assessment)



Mikael Hagelin
Certification Authority (Audit)

PRODUCT LIST FOR CERTIFICATE

Issued to: Medlab Media Group, MMG

Certificate number: 28620156616

Certificate valid from: 2023-09-13

Product List Issue Date:
13 September 2023

Product	Classification and EMDN	Intended use[1]	Date Added
Computed Tomography Software - Dental			
Basic UDI-DI: 843604688DentomoXU			
40000015 - Dentomo	Class IIa		2023-09-13

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.