

EC CERTIFICATION

EU 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, restricted to the aspects relating to the conformity of the devices with reusability requirements, 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.

Transamerican Technologies International dba TTI Medical

220 Porter Drive Suite 120 San Ramon, California 94583 United States

Manufacturer SRN: US-MF-000007955

Authorised Representative Name

QNET B.V. [NL]

19, Kantstraat, 5060 GA, Haaren-Oisterwijk, 10110 Netherlands

Scope:

Reusability aspects of devices as detailed in attached product list

Certificate Number:
28620235533

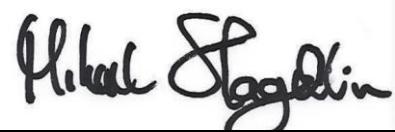
Revision:
00

Initial Certification Date:
13 January 2026

Certificate Decision Date:
13 January 2026

Certificate Issue Date:
13 January 2026

Certificate Expiry Date:
28 June 2030



Mikael Hagelin
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

Last Audit report reference	
Stage 1 ACTY-2024-205450	
Stage 2 ACTY-2024-205454	

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620235533	13 January 2026	Initial certificate


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PRODUCT LIST FOR CERTIFICATE

Issued to: Transamerican Technologies International
dba TTI Medical

Certificate number: 28620235533

Certificate valid from: 2026-01-13

Product list issue date:
13 January 2026

Product	Classification and EMDN	Intended use ¹	Date Added
Class I Reusable Instruments			
Basic UDI-DI: ++B177055Y			
91010 - Fiberoptic Handpiece R	Class I(r) L030199		2026-01-13
9111-13 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9111-14 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9111B-12 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9111B-13 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9111B-14 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9111B - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9111 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9112-13 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9112-14 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9112B-12 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9112B-13 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9112B-14 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13

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



Product	Classification and EMDN	Intended use ¹	Date Added
9112B - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9112 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9113-14 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9113B-13 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9113B-14 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9113B - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9113 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9114-17-15 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9114B-14 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9114B - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9114 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9121 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9122 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9123 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9131 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9132 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9141 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9151 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9152 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9153 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9154B - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13

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Product	Classification and EMDN	Intended use ¹	Date Added
9154 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9155 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9162-14 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9162-16 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9163-14 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9171 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9172 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9181 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9182 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9183 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9185-1BS - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9185-1S - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9185-2BS - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9190 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9191 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9192 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9193 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9194 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9195 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9196 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13

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Product	Classification and EMDN	Intended use ¹	Date Added
9197 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9198 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9199 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9202-17 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9202 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9203-17 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9203 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9204-17 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9204 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9205-17 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9205 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9206-17 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9206 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9207-17 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9207 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9208-17 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9208 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9209-17 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9209 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9211 - Fiberoptic Handpiece Dental	Class I(r) L030199		2026-01-13
9212 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13

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Product	Classification and EMDN	Intended use ¹	Date Added
9212M - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9213 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9213M - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9214 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9214M - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9215 - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9215M - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
9501-34/70 - Fiber Director	Class I(r) L030199		2026-01-13
9501-50/70 - Fiber Director	Class I(r) L030199		2026-01-13
AC-140mm M - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
AC-240mm M - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
AC-300mm M - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
AC-90mm M - Fiberoptic Handpiece	Class I(r) L030199		2026-01-13
Basic UDI-DI: 0860009714905UM			
AC-1059620 - FiberLase GYN LAP-R	Class I(r) L030199		2026-01-13
AC-1059630 - FiberLase GYN LAP-S	Class I(r) L030199		2026-01-13
AC-2059620 - SS FiberLase GYN LAP-R	Class I(r) L030199		2026-01-13
AC-2059630 - SS FiberLase GYN LAP-S	Class I(r) L030199		2026-01-13

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