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.

Certificate Number:
28620147149

Revision:
00

Initial Certification Date:
19 April 2023

Certificate Decision Date:
19 April 2023

Certificate Issue Date:
19 April 2023

Certificate Expiry Date:
18 April 2028

Pyrexar Medical Inc

1825 W Research Way, Unit E, Salt Lake City, Utah, 84119, United States

Manufacturer SRN: US-MF-000026753

Authorised Representative Name

Obelis S.A

Bd. General Wahis, 53 – 1030 Brussels, Belgium

Scope:

RF Hyperthermia Cancer Treatment Systems

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	**TD00075-01 Pyrexar Medical Inc Deep Regional RF Hyperthermia System**
Audit Report Reference	**Stage 1 audit ACTY-2021-470495**
	Stage 2 audit ACTY-2021-470496
	Special Surveillance audit ACTY-2022-564209

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620147149

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MDR – Decision Report

Certificate No: 28620147149
Date: 19 April 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Pyrexar Medical Inc
Attn: Debbie Carlson
1825 W Research Way , Unit E,
Salt Lake City,
Utah, 84119,
United States

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-2021-470495	Salt Lake City	Levent Durukan	21 – 22 April 2022
Stage 2 ACTY-2021-470496	Salt Lake City	Luis Lopes Alexander Crosby	19 – 22 July 2022
Special Surveillance ACTY-2022-564209	Salt Lake City	Luis Lopes	26 August 2022

Technical Documentation Report	Assessor Name	Assessment Date
FINAL TDAR_Pyrexar_TD00075-01_2023-02-08	Sharmila Gardner	8 February 2023
FINAL CEAR_Pyrexar_TD00075-01_2023-02-08	Sharmila Gardner	8 February 2023

Scope of assessment

Product category, Class

Result

2 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(s) have been closed.

Certificate Valid from

19 April 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: Pyrexar Medical Inc

Certificate number: 28620147149

Certificate valid from: 2023-04-19

Product List Issue Date:
19 April 2023

Product	Classification and EMDN	Intended use[1]	Date Added
RF Hyperthermia Cancer Treatment Systems			
Basic UDI-DI: 08644450004BSD-20002G			
BSD-2000 - Deep Regional RF Hyperthermia System	Class IIb Z120402	The BSD-2000 system is a prescription device that is intended to deliver hyperthermia, which has been shown to increase the sensitivity of tumor cells to radiation or chemotherapy by the external application of electromagnetic energy. The system provides hyperthermia to solid tumors by generating and applying radio frequency (RF) energy.	2023-04-19
Basic UDI-DI: 8644450004BSD-500V9			
BSD-500 - Superficial/Interstitial RF Hyperthermia System	Class IIb Z120402	The BSD-500 Hyperthermia System delivers therapeutic heat to certain surface or subsurface malignant tumors by the external or interstitial application of electromagnetic energy and monitors the temperature of target and surrounding tissues by means of independent temperature sensors.	2023-04-19

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