



CERTIFICATE

EC Certificate No. 1434-MDD-235/2019
Production Quality Assurance

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Exergen Corporation

**400 Pleasant Street, Watertown, MA 02472,
United States**

for the design, manufacture and final inspection of medical devices, class IIa

Infrared thermometers
Model Type: TAT 5000 series

complies with requirements
of Annex V 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 06.05.2019 to 16.11.2020

The date of issue of the Certificate: 06.05.2019



Application No: 759/2019
Module D

Michał Pachowski. Ph.D.
President



Certificate No. **1434-MDD-235/2019**
Issued under the Contract No. **MD-80/2019**
Bears the PCBC hologram
Warszawa, 06/05/2019



Polskie Centrum Badań i Certyfikacji S.A.

Warsaw, 13.05.2019

BM/...⁵⁵⁴...../2019/ASo

Mr. Jim Casamento
Exergen Corporation
400 Pleasant Street
Watertown, MA 02472 UNITED STATES

Transfer of Certificates from UL (Notified Body 0843) to PCBC (Notified Body 1434) in Poland

This document confirms that UL is working in partnership with PCBC to transfer UL CE marking activities to PCBC and that the transfer has now been completed for this customer.

A "like for like" transfer procedure has been completed according to PCBC processes and procedures according to NBOG guidance http://www.doks.nbog.eu/Doks/NBOG_BPG_2006_1.pdf

The PCBC certificate describes the scope and products approved, the original expiration date of the certificate has been preserved as required by the guidance.

PCBC will now take over the CE conformity assessment activities for this customer and has access to customer conformity assessment history and will continue the established on-market surveillance activities without interruption. In line with NBOG guidance the manufacturer now has 6 months to transition their labelling to PCBCs notified body number and therefore product labeled with the UL *Notified Body number can be sold under the PCBC certificate.

Yours Sincerely,
Director
of Medical Devices
Certification Department


Adam Sobantka