
	<b>Declaration of Conformity</b> <b>Exergen Disposable Caps</b>	<b>Document No.:</b> <b>TD-1061</b>
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### Declaration of Conformity

<b>MANUFACTURER</b>	Exergen Corporation 400 Pleasant Street Watertown, MA 02472 USA
<b>SRN OF MANUFACTURER</b>	US-MF-000011488E
<b>EUROPEAN REPRESENTATIVE</b>	Emergo Europe B.V. Westervoortsedijk 60 Arnhem 6827 AT Netherlands
<b>SRN OF EUROPEAN REPRESENTATIVE</b>	NL-AR-000000116
<b>BASIC UDI-DI</b>	083409800134203BP
<b>PRODUCT NAME</b>	Exergen Disposable Caps
<b>RISK CLASSIFICATION WITH RULE</b>	Class I, Rule 1
<b>INTENDED PURPOSE</b>	The disposable caps are intended to be used with Exergen Temporal Scanner Thermometers to prevent cross-contamination (from one patient to another).
<b>COMMON SPECIFICATIONS APPLIED</b>	Not Applicable
<b>CONFORMITY ASSESSMENT PROCEDURE</b>	Annex IX, Chapter I and Chapter III
<b>CERTIFICATE NUMBER</b>	Not Applicable, Self-Declaration

### SCHEDULE OF INCLUDED MEDICAL DEVICES

Product Name	Part Number	UDI	Product Description
Disposable Caps	134203	10834098000904	Package of 1000 Disposable Caps for TAT-2000, TAT-5000S Thermometer, Clinical
Disposable Caps	134205	10834098000911	Package of 5000 Disposable Caps for TAT-2000, TAT-5000S Thermometer, Clinical
Disposable Caps	134204	10834098000935	Package of 50 Disposable Caps for TAT-2000, TAT-5000S Thermometer, Clinical
Disposable Caps	134208	10834098000942	Package of 250 Disposable Caps for TAT-2000, TAT-5000S Thermometer, Clinical

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# DECLARATION STATEMENT

We herewith declare that this EU declaration of conformity is issued under the sole responsibility of Exergen Corporation. The device(s) covered by present EU declaration of conformity is in conformity with the European Union Medical Device Regulation 2017/745.

## PLACE OF ISSUE:

400 PLEASANT ST WATERTOWN, MA 04472

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**Signature**

**Name:** Tanya Porter

30 May 2023 .....  
**Date** (dd/mm/yyyy)

**Title:** Director of Quality and Regulatory Management

Person Responsible for Regulatory Compliance  
Signed for and on behalf of Exergen Corporation