



Notified Body 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,**  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## EC Certificate - Production Quality Assurance No. 19 0248 QS/NB

The quality system of manufacturer

**Wuxi Medical Instrument Factory Co., Ltd.**

**No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City,  
Jiangsu 214194 China**

has been certified as meeting the requirements of

**Directive 93/42/EEC**  
**on medical devices, Annex V**

for the following product category(ies):

**Mercury free clinical thermometer**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. The Notified Body has audited this system with limitation to those aspects of manufacture concerned with the conformity of the devices with metrological requirements. This part of quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance.

**Valid from:** 2019-05-22  
**Valid until:** 2024-05-21  
**First Issued:** 2019-05-22  
**Revision:** -



Date: 2019-05-22

**Mgr. Jiří Heš**  
Representative of the Notified Body No. 1023



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**Annex to EC Certificate No. 19 0248 QS/NB**  
issued for manufacturer:

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**Jiangsu 214194 China**

**Product(s):**

|                       |                                          |
|-----------------------|------------------------------------------|
| <b>Name:</b>          | <b>Mercury free clinical thermometer</b> |
| <b>Trade name(s):</b> | Mercury free clinical thermometer        |
| <b>Model(s):</b>      | CR.W00                                   |
| <b>Class:</b>         | Im                                       |
| <b>GMDN:</b>          | 34343                                    |

**Facility(ies):**

Wuxi Medical Instrument Factory Co., Ltd.  
No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City, Jiangsu 214194 China



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**Certificate History:**

| Revision | Date       | Reference Number | Action        |
|----------|------------|------------------|---------------|
|          | 2019-05-22 | 803602800        | Certification |
|          |            |                  |               |
|          |            |                  |               |



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