



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

**Kaz USA, Inc.,**  
A Helen of Troy Company

400 Donald Lynch Boulevard  
Marlborough, MA, 01752  
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

## Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Device	Class
PRO 6000 Braun ThermoScan® thermometer	Ila
Probe covers / Lens filters	Ila

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no. 469609 MR2  
Certificate unique ID 170646308  
Effective date 2016-07-18  
Expiry date 2021-07-17  
Frankfurt am Main 2016-07-18

### DQS Medizinprodukte GmbH

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Dr. Thomas Feldmann  
Head of Certification Body

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

