



EC-CERTIFICATE



(Production quality assurance)

This is to certify that the company

Kaz USA, Inc.

250 Turnpike Road, Southborough MA 01772 United States of America

has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

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

Annex V of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

PRO 6000 Braun ThermoScan® thermometer IIa
PRO 4000 IR thermometer series IIa
Probe covers / Lens filters IIa
V980 / BET 1000 medical thermometer IIa

The manufacturer is subject to surveillance according to Annex V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the 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 MR5
Certificate unique ID 170623455
Effective date 2015-05-22
Expiry date 2018-10-17
Frankfurt am Main 2015-05-22

DQS Medizinprodukte GmbH

Frank Graichen Managing Director

Dr. Thomas Feldmann Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

