



EC-CERTIFICATE

(Production quality assurance)



This is to certify that the company

ITP Innovative Tomography Products GmbH

Universitätsstraße 136
44799 Bochum
Germany

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:

Coaxial Interventional Needle KIR/ KIM	Class IIa
Semi-automatic Biopsy-Needle BIM	Class 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.	535006 MR5
Certificate unique ID	170774119
Effective date	2021-02-01
Expiry date	2024-05-26
Frankfurt am Main	2021-02-01

DQS Medizinprodukte GmbH

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