EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

PROTEC GmbH & Co. KG

In den Dorfwiesen 14
71720 Oberstenfeld
Germany

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:

Application software for picture archiving, picture communication and image processing systems in diagnostic radiology and for imaging methods, Conversion systems for digital imaging in diagnostic radiology, Analogue and digital, stationary and mobile, basic diagnostic x-ray systems according to annex.

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.	375503 MR2
Certificate unique ID	170775732
Effective date	2021-04-16
Expiry date	2023-10-11
Frankfurt am Main	2021-04-16

Digitally signed by Matei Vasile
Date: 2023.08.16 18:35:50 EEST
Reason: MoldSign Signature
Location: Moldova

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.

411.20 Version 1.0

Annex to certificate
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Device family	Device	UMDNS Code	Class
Software for image data acquisition, processing, transmission, diagnosis and archiving (Radiology)	CONAXX 2	16-247	IIb
Software for image data processing, transmission, diagnosis and archiving (Radiology)	PROPAXX	16-247	IIb
Digital X-ray detector system	RAPIXX DR-System	17-904	IIb
Stationary basic diagnostic X-ray systems, analogue or digital	PRS 500	13-271	IIb
	PRS 500 B	13-271	IIb
	PRS 500 C	13-271	IIb
	PRS 500 E	13-271	IIb
	PRS 500 F	13-271	IIb
	PRS 500 X	13-271	IIb