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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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

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
Certificate registration No.: 375503 MR2
Certificate unique ID: 170775732
Effective date: 2021-04-16

PROTEC GmbH & Co. KG

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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

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

PROTEC GmbH & Co. KG

In den Dorfwiesen 14

71720 Oberstenfeld

Germany

2023-11-16

Notified Body Confirmation Letter

Reference: 370503

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical device

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

PROTEC GmbH & Co. KG

In den Dorfwiesen 14

71720 Oberstenfeld

Germany

SRN: DE-MF-000006341

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Stefan Theuss

Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CONAXX 2: 426050264D002UZ	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate registration number: 375503 MR2 Certificate ID: 170775732 NB identification: 0297
PRS 500 Serie **(PRS 500 B: 426050264X001ZB;** **PRS 500 C: 426050264X002ZD;** **PRS 500 E: 426050264X005ZK;** **PRS 500 F: 426050264X006ZM;** **PRS 500 X: 426050264X007ZP)**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate registration number: 375503 MR2 Certificate ID: 170775732 NB identification: 0297

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-11-16	170764183	Initial issue
	Cert-ID	description of change (e.g. addition of device XYZ to Table 1)
	Cert-ID	description of change (e.g. removal of device XYZ from Table 2)