CERTIFICATO CE

Certificato n. 1916/MDD

MOD 1475A / 2

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

TECHNIX SPA

24050 GRASSOBBIO (BG) - VIA E. FERMI 45 (ITA) - Italy

mantiene negli stabilimenti di:

24050 GRASSOBBIO (BG) - VIA E. FERMI 45 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Apparecchiature mobili per radiologia
Modd. PROSLIDE 32 B; PROSLIDE 32 SR.
Marca PROTEC

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II.

Riferimento pratiche IMQ:
DM16-0004422-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2016-11-25

Data Scadenza: 2021-04-27

IMQ

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".

MOD. 1475A / 2

EC CERTIFICATE

Certificate No 1916/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

TECHNIX SPA

24050 GRASSOBBIO (BG) - VIA E. FERMI 45 (ITA) - Italy

manages in the factories of:

24050 GRASSOBBIO (BG) - VIA E. FERMI 45 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Mobile radiographic units
Type ref. PROSLIDE 32 B; PROSLIDE 32 SR.
Trade mark PROTEC

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II.

Reference to IMQ files Nos:
DM16-0004422-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date: 2016-11-25

Expirying Date: 2021-04-27

IMQ

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

CERTIFICATE

This is to certify that the company

PROTEC
TEAM | SPIRIT | ABILITY

PROTEC GmbH & Co. KG

In den Dorfwiesen 14
71720 Oberstenfeld
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Design and development, production, sales, installation and service of:
Automated x-ray film processors and accessories,
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,
Components and accessories for basic diagnostic x-ray systems.

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

DIN EN ISO 13485 : 2016 + Ber. 1:2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	375503 MP2016
Certificate unique ID	170704464
Effective date	2018-10-12
Expiry date	2021-10-11
Frankfurt am Main	2018-10-12

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

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

CERTIFICATE

This is to certify that

PROTEC
TEAM | SPIRIT | ABILITY

PROTEC GmbH & Co. KG

In den Dorfwiesen 14
71720 Oberstenfeld
Germany

has implemented and maintains a **Quality Management System**.

Scope:
In the sectors of human medicine, veterinary medicine and non-destructive testing / NDT for the Design and development, production, sales, installation and service of:
Automated x-ray film processors and accessories,
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,
Components and accessories for basic diagnostic x-ray systems.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	375503 QM15
Certificate unique ID	170704463
Effective date	2018-10-12
Expiry date	2021-10-11
Frankfurt am Main	2018-10-12

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-16021-02-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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

401 94 Version 2.0

CE 0297

EG-Konformitätserklärung
EC Declaration of Conformity

PROTEC
TEAM SPIRIT ABILITY

Der Hersteller PROTEC GmbH & Co. KG erklärt, dass die Produkte
The manufacturer PROTEC GmbH & Co. KG declares, that the products

Handelsname
Trade Name

RAPIXX DR-System

Generische Produktgruppe
Generic product group

Umwandlungssystem für die digitale Bildgebung in der diagnostischen Radiologie
Diagnostic x-ray digital imaging conversion system

Modelle *Models*	Artikelnummern *Catalogue numbers* REF	Modelle *Models*	Artikelnummern *Catalogue numbers* REF
RAPIXX 4336M1i WiFi Set	(4451-9-0000L)	RAPIXX 4336M1F ES WiFi Set	(4553-9-0000L)
RAPIXX 4343M1i WiFi Set	(4453-9-0000L)	RAPIXX 4336M2F ES WiFi Set	(4554-9-0000L)
RAPIXX 4343M1i X CC Set	(4552-9-0000L)	RAPIXX 4343M1F ES WiFi Set	(4555-9-0000L)
RAPIXX 4343M1V CC Set	(4456-9-0000L)	RAPIXX 4343M2F ES WiFi Set	(4556-9-0000L)
RAPIXX 4343M2V CC Set	(4457-9-0000L)	RAPIXX 4336M1F ES CC Set	(4557-9-0000L)
RAPIXX 4336M1V v4 WiFi Set	(4470-9-0000L)	RAPIXX 4336M2F ES CC Set	(4558-9-0000L)
RAPIXX 4336M2V v4 WiFi Set	(4474-9-0000L)	RAPIXX 4343M1F ES CC Set	(4559-9-0000L)
		RAPIXX 4343M2F ES CC Set	(4560-9-0000L)

Klassifizierung / *Classification*

Klasse IIb (nach RL 93/42/EWG Anhang IX; Regel 10)
Class IIb (according to Directive 93/42/EEC Annex IX; Rule 10)

den Anforderungen der **Richtlinie 93/42/EWG über Medizinprodukte** entsprechen, die anwendbar sind (einschließlich aller zum Ausstellungsdatum gültigen Änderungsrichtlinien).
*meet the provisions of **Medical Device Directive 93/42/EEC** which apply to them (including all valid amendments to the date of issue).*

Die Konformitätsbewertung erfolgt nach dem Verfahren gemäß Anhang II der o.g. Richtlinie.
Conformity assessment is carried out in accordance with the procedure set out in Annex II of the Directive above.

Am Konformitätsbewertungsverfahren beteiligte Benannte Stelle:
Notified Body involved in the conformity assessment procedure:

DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main, Nr. 0297

Diese Erklärung ist gültig bis:
Expiry date of this declaration:

2021-10-11

In alleiniger Verantwortung für die Ausstellung dieser Erklärung:
Under sole responsibility for issuing this declaration:

PROTEC GmbH & Co. KG
In den Dorfwiesen 14
71720 Oberstenfeld
Germany

Oberstenfeld, 2019-03-29
Unterschrift / Signature:

Frank Baisch
Managing Director Technology