

The manufacturer PROTEC GmbH & Co. KG, SRN DE-MF-000006341, declares herewith, that the products

Basic UDI-DI 426050264X001ZB, 426050264X002ZD  
426050264X005ZK, 426050264X006ZM, 426050264X007ZP

Trade names **PRS 500 B, PRS 500 C,  
PRS 500 E, PRS 500 F, PRS 500 X**

Generic product groups Stationary basic diagnostic x-ray systems, analogue or digital

Product codes EMDN/CND Z11039005  
GMDN 37644 / 37645

Intended purpose The basic diagnostic X-ray systems of the PRS 500 series are intended for various routine applications in planar X-ray imaging in human medicine. They are stationary systems that can be used both for analogue and digital imaging.

Catalogue numbers  70xx-9-xxxx\_Vxxx  
x stands for a number between 0 and 9

Risk class Class IIb (according to Directive 93/42/EEC Annex IX; Rule 10)

meet the provisions of **Medical Device Directive 93/42/EEC** which apply to them (including all valid amendments to the date of issue).

Conformity assessment is carried out in accordance with the procedure set out in Annex II of the Directive above.

Notified Body involved in the conformity assessment procedure according to MDD:

**DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main,  
identification number: 0297**

Marking of the certificates issued: 375503 MR2  
375503 MP2016

Furthermore PROTEC declares herewith, that, depending on their configuration, the products meet the provisions which apply to them of the following other relevant Union legislation that provide for the issuing of an EU declaration of conformity:

Directive 2006/42/EC on machinery

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment

Expiry date of this declaration: 2023-10-11

Under the sole responsibility for issuing this declaration:

For and on behalf of

Oberstenfeld, 2021-05-24  
Signature:

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



Frank Baisch  
Managing Director Technology