# Statement according to Article 22 of Regulation (EU) 2017/745

for

## RAPIXX DR-System

| | | |
|---|---|---|
| Basic UDI-DI | | 426050264D001UX |
| Catalogue numbers | REF | 4999-9-0000_Vxxx<br>x stands for a number between 0 and 9 |

The systems are put together of the following medical devices bearing the CE marking:

| Product group | Trade name(s) | Manufacturer | Legal basis | Class | CE marking | Expiry date EC-Certificate |
|---|---|---|---|---|---|---|
| X-ray image acquisition software | CONAXX 2 | PROTEC | MDD | IIb | CE 0297 | 2023-10-11 |
| DR detectors | Mars1417V3-TSI | iRay | MDD | IIa | CE 0197 | 2024-05-26 |
| | Mars1717V3-VSI | iRay | MDD | IIa | CE 0197 | 2024-05-26 |
| | Venu1717X | iRay | MDD | IIa | CE 0197 | 2024-05-26 |
| | Mars1417X | iRay | MDD | IIa | CE 0197 | 2024-05-26 |
| | Mars1717X | iRay | MDD | IIa | CE 0197 | 2024-05-26 |
| | FDR ES C35 | Fujifilm | MDD | IIa | CE 0123 | 2023-05-13 |
| | FDR ES G35 | Fujifilm | MDD | IIa | CE 0123 | 2023-05-13 |
| | FDR ES C43 | Fujifilm | MDD | IIa | CE 0123 | 2023-05-13 |
| | FDR ES G43 | Fujifilm | MDD | IIa | CE 0123 | 2023-05-13 |
| DR system interface component | INTERFACE BOX | PROTEC | MDR | I | CE | n/a |

We hereby state that we combine the devices together in a manner that is compatible with the intended purpose of the devices and within the limits of use specified by their manufacturers, in order to place them on the market as systems. We have verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions.

We package the systems and supply relevant information to users incorporating the information to be supplied by the manufacturers of the devices, which have been put together. The activity of combining devices as systems was subject to appropriate methods of internal monitoring, verification and validation.

Under sole responsibility for issuing this statement:

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Oberstenfeld, 2022-02-02

Frank Baisch
Managing Director Technology

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