Add value.
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TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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Your reference/letter of	Our reference/name	Tel. extension/Email	Mobile	Date	Page
	PS-MHS-RM-17/ Max Huhn	+49 89 50084-840 Max.Huhn@tuvsud.com	+4915111540712	2024-05-21	1 of 2

TÜV SÜD Product Service GmbH
Receipt of formal application

Reference: 200130019105

To whom it may concern,

Confirmation of the status of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received **a formal application** in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: HU-MF000008177

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.
To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-21

Max Huhn (22. Mai 2024 13:08 GMT+2)

Max Huhn
Customer Relationship Manager
PS-MHS-RM-17

Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device Name	Variant/Type	Article No.	Basic UDI-DI
Perform-X Radiographic System	Perform-X	Perform-X (Classic)	5999116100211111R5
Perform-X Radiographic System	Perform-X F100 Floor Mounted system	PERFORM-X F100	5999116100211111R5
Perform-X Radiographic System	Perform-X F200 Floor Mounted system	PERFORM-X F200	5999116100211111R5
Perform-X Radiographic System	Perform-X F300 Floor Mounted system	PERFORM-X F300	5999116100211111R5
Perform-X Radiographic System	Perform-X F400 Floor Mounted system	PERFORM-X F400	5999116100211111R5
Perform-X Radiographic System	Perform-X C100 Ceiling Mounted system	PERFORM-X C100	5999116100211111R5
Perform-X Radiographic System	Perform-X C200 Ceiling Mounted system	PERFORM-X C200	5999116100211111R5
Perform-X Radiographic System	Perform-X C300 Ceiling Mounted system	PERFORM-X C300	5999116100211111R5
Perform-X Radiographic System	Perform-X C400 Ceiling Mounted system	PERFORM-X C400	5999116100211111R5
Perform-X Radiographic System	RadioLogiX Radiographic System	RadioLogiX	5999116100211111R5
Camargue Radiographic System	Camargue Classic Radiographic system	Z7J32003	5999116100211111R5
Camargue Radiographic System	Camargue F200 Floor Mounted system	Z7J32004	5999116100211111R5
Camargue Radiographic System	Camargue F300 Floor Mounted system	Z7J32005	5999116100211111R5
Camargue Radiographic System	Camargue C200 Ceiling Mounted system	Z7J32006	5999116100211111R5
Camargue Radiographic System	Camargue C300 Ceiling Mounted system	Z7J32007	5999116100211111R5
Z-Motion Radiographic System	Z-Motion	8611	599911610221111YK
COBRA Mobile Radiographic System	-/-	N/A	599911610231111M6