Certificate No: AMBV-CE-MDR14

CERTIFICATE *of* CE (MDR)NOTIFICATION

THIS IS TO NOTIFY THAT AMSTERMED BV IN ACCORDANCE WITH MDR 2017/745 AGREES TO BE THE AUTHORISED REPRESENTATIVE AND AGREES TO PERFORM ALL DUTIES AND RESPOSIBILITIES FOR

AmbalSoft InfoTech Private Limited

New No: 32, Old No: 11, Pitchu Street, Mylapore,
Chennai - 600004. Tamil Nadu. INDIA

AS STIPULATED AND AFOREMENTIONED DIRECTIVE.

The manufacturer declares that the devices enlisted in Annex A are Class I and comply with the directive requirements including the general safety and performance requirements.

The manufacturer has provided Amstermed BV with all appropriate declarations and adequate documentation as required by the Council Regulation 2017/745 MDR article 57.4 requirements, including EC declaration of conformity (According to Annex IV) confirming that their Class I medical devices, as stipulated here below, are fulfilling the applicable Council Regulation 2017/745.
The notification of the following medical devices has been completed by Amstermed BV on 22/09/2022 on compliance with the Council Regulation 2017/745 MDR article 57.4 requirements.
Class I Medical devices: Please see Annex A – List of devices (1 Page, 1 device).
Any significant changes in the Design or Process used to manufacture the Product, or revision to the Directives or standards referred above may require notification to Amstermed BV. The product liability rests with the Manufacturer in accordance with Council Directive.
As of 22/09/2022, and as long as the Manufacturer will continue complying with the hereabove mentioned requirements**, he therefore:

- Is required to affix the CE marking on the devices;
- May place these devices in the European EU and EEA territory.

SEP, 22 2022

SIGNED, *Mike Vermin*, CEO

Amstermed B.V.
The Netherlands
VAT no: NL860216391B01
www.amstermed.nl

Certificate No: AMBV-CE-MDR14

Annex A: List of Devices

#	Product Name	GMDN Code	EMDN Code	NOTIS Registration Number	Variants	Brand Name	Class	Rule
1	CaptureITPro Medical Imaging Software	60723	Z12020492	20226036	NA	CaptureITPro	1	11

SIGNED, *Mike Vermin*, CEO Amstermed B.V.
The Netherlands
VAT no: NL860216391B01
www.amstermed.nl

CE
SEP, 22 2022

Certificate No: AMBV-CE-MDR20

CERTIFICATE *of* CE (MDR)NOTIFICATION

THIS IS TO NOTIFY THAT AMSTERMED BV IN ACCORDANCE WITH MDR 2017/745 AGREES TO BE THE AUTHORISED REPRESENTATIVE AND AGREES TO PERFORM ALL DUTIES AND RESPOSIBILITIES FOR

AMBALSOFT INFOTECH PRIVATE LIMITED

#32 PITCHU STREET, MYLAPORE,
CHENNAI – 600004. TAMILNADU, INDIA

AS STIPULATED AND AFOREMENTIONED DIRECTIVE.

The manufacturer declares that the devices enlisted in Annex A are Class I and comply with the directive requirements including the general safety and performance requirements.

The manufacturer has provided Amstermed BV with all appropriate declarations and adequate documentation as required by the Council Regulation 2017/745 MDR article 57.4 requirements, including EC declaration of conformity (According to Annex IV) confirming that their Class I medical devices, as stipulated here below, are fulfilling the applicable Council Regulation 2017/745.
The notification of the following medical devices has been completed by Amstermed BV on 29/06/2021 on compliance with the Council Regulation 2017/745 MDR article 57.4 requirements.
Class I Medical devices: Please see Annex A – List of devices (1 Page, 1 device).
Any significant changes in the Design or Process used to manufacture the Product, or revision to the Directives or standards referred above may require notification to Amstermed BV. The product liability rests with the Manufacturer in accordance with Council Directive.
As of 29/06/2021, and as long as the Manufacturer will continue complying with the hereabove mentioned requirements**, he therefore:

- Is required to affix the CE marking on the devices;
- May place these devices in the European EU and EEA territory.

Amstermed B.V.
The Netherlands
VAT no: NL860216391B01
www.amstermed.nl

JULY, 30 2025

SIGNED, *Mike Vermin*, CEO

Certificate No: AMBV-CE-MDR20

Annex A: List of Devices

#	Product Name	GMDN Code	NOTIS Registration Number	Model	Class	Rule
1	COLPOITPRO COLPOSCOPY IMAGING SOFTWARE	60723	20251986	ColpoITPro	1	1

AMSTERMED

CE

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www.amstermed.nl

SIGNED, *Mike Vermin*, CEO

JULY, 30 2025