

Certificate No: AMBV-CE-MDR09

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 RESPONSIBILITIES FOR

Cephas Medical Private Limited

Site 1: Plot B-13, Phase-1, MEPZ-SEZ, Tambaram,
Kanchipuram, Tamil Nadu (India)- 600045

Site 2: Plot B-21, Phase-1, MEPZ-SEZ, Tambaram,
Kanchipuram, Tamil Nadu (India)- 600045

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.

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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.

SIGNED, *Mike Vermin*, CEO

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Annex A: List of Devices

#	Product Name	GMDN Code	NOTIS Registration Number	Variants	Brand Name	Class	Rule
1	Silicone Male External Catheter	34929	20214410	Self adhesive / Without adhesive in sizes - Small, Medium, Intermediate, Large , Extra Large	Cephas	1	1

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SIGNED, Mike Vermin, CEO