

Certificate No: AMBV-CE-IVDR30

CERTIFICATE *of* CE (IVDR)NOTIFICATION

THIS IS TO NOTIFY THAT AMSTERMED BV IN ACCORDANCE WITH IVDR 2017/746 AGREES TO BE THE
AUTHORISED REPRESENTATIVE AND AGREES TO PERFORM ALL DUTIES AND RESPONSIBILITIES FOR

STRUmed Solutions Private Limited

Plot No.44, Ichhapore GIDC Industrial Estate,
Bhatpore, Off Hazira Road, behind Tata
Motors, Surat, Gujarat 394510, India.

AS STIPULATED AND AFOREMENTIONED DIRECTIVE.

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



SEPTEMBER, 12 2025

The manufacturer has provided Amstermed BV with all appropriate declarations and adequate documentation as required by the Council Regulation 2017/746 IVDR article 52 requirements, including EC declaration of conformity (According to Annex IV) confirming that their Class A medical devices, as stipulated here below, are fulfilling the applicable Council Regulation 2017/746. The notification of the following In-vitro diagnostic medical devices has been completed by Amstermed BV on 29/06/2021 on compliance with the Council Regulation 2017/746 IVDR article 52 requirements.

Class A In-vitro diagnostic 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.

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Annex A: List of Devices

#	Product Name	GMDN Code	NOTIS Registration Number	Model Name	Model Number	Class
1	Nephelometer	56676	20252725	iNSTA XPLOR® P	PA001	A



AMSTERMED



SIGNED, Mike Vermin, CEO

SEPTEMBER, 12 2025