Certificate No: AMBV-CE-IVD05

CERTIFICATE *of* CE (IVD)NOTIFICATION

THIS IS TO NOTIFY THAT AMSTERMED BV IN ACCORDANCE WITH IVD 98/79/EEC AGREES TO BE THE AUTHORISED REPRESENTATIVE AND AGREES TO PERFORM ALL DUTIES AND RESPOSIBILITIES FOR

Strumed Solutions Private Limited
1st Floor, Module No. 06 - BTCIF, TICEL Bio Park - Phase II, CSIR Road,
Taramani, Chennai, 600113 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 essential requirements.

The manufacturer has provided Amstermed BV with all appropriate declarations and adequate documentation as required by the Council Directive 98/79/EEC article 09 requirements, including EC declaration of conformity (According to Annex III) confirming that their Non-Listed IVD medical devices, as stipulated here below, are fulfilling the applicable Council Directive 98/79/EEC.
The notification of the following medical devices has been completed by Amstermed BV on 07/01/2021 on compliance with the Council Directive 98/79/EEC-article 10 requirements. For serial number 01 of Annex 1 the notification process was completed on 16/10/2020.
Non-Listed IVD devices: Please see Annex A – List of devices (1 Page, 2 device).
Any significant changes in the Design or Process u sed to manufacture the Product, or revision to the Directives or standard s referred above shall require notification to Amstermed BV. The product liability rest s with the Manufacturer in accordance with Council Directive.
As of 07/01/2021, and as long as the Manufacturer will continue complying with the hereabove mentioned requirement s**, he therefore:
- Is required to affix the CE marking on the devices;
- May place these de vices in the European EU and EEA territory.

CE

JANUARY, 21, 2021

SIGNED, *Mike Vermin*, CEO

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

*** This certificate will become void if it is rejected by any EU Authorities or upon termination with EAR Agreement.*

Certificate No: AMBV-CE-IVD05

Annex A: List of Devices

#	Product Name	GMDN Code	CIBG Registration Number	NOTIS Registration Number	Variants	Brand Name	Class	Rule
1	Viral Transport Medium	15743	NL-CA002-2020-53832	20204967	NA	iNSTA XPORT	Non-Listed IVD	Not Applicable
2	COVID 19 RAPID ANTIGEN TEST	48247	NL-CA002-2021-55423	20210103	NA	INSTA XPLOR	Non-Listed IVD	Not Applicable

SIGNED, *Mike Vermin*, CEO

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CE

JANUARY, 21, 2021