CE Notification Confirmation

This is to confirm that, according to the council directive 98/79/EC, SUNGO Europe B.V. performed the notification duties and responsibilities as the European authorized representative of:

HEBEI CHAORAN MEDICAL INSTRUMENTS CO., LTD
Hanxilou, Xiong County, Xiongan New Area, Hebei Province, China

The Manufacturer has provided SUNGO Europe B.V. with the EC Declaration of Conformity confirming that the In Vitro Diagnostic Medical Device (IVDD), as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 98/79/EC.

According to 98/79/EC, the European Databank on Medical Devices (EUDAMED) is established as of May 1 2011. The Netherlands Competent Authority is notified of the manufacturer's In Vitro Diagnostic Medical Device and has allocated registration number.

Disposable Blood Collection Tube

Not in List A and List B according to Annex II of 98/79/EC

GMDN CODE : 35770

CIBG Number: NL-CA002-2020-50786

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This document should be used together with the competence authority notification letter and the Declaration of Conformity issued by the Manufacturer. This document will become to be invalid once the notification status is changed or the EAR agreement is terminated.

Reference Number: EUCAN00281
Issue date: May, 11, 2020

For and on behalf of
SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Authorized Signature
Only used for the EU Representative Signature

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