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1 Document Approval - Electronic Signatures

Christos Freris;Document Control Review;May 10, 2021 9:19 AM EEST
Achilleas Tsoukalis;Review;May 15, 2021 10:53 PM EEST
Sasa Karpeti;Final Approval;May 17, 2021 9:10 AM EEST
Christos Freris;Final Approval;May 17, 2021 10:57 AM EEST

2 Declaration of Conformity

We,

the medical device manufacturer,

Micrel Medical Devices S.A.
42 Konstantinoupoleos Str.
Koropi/Athens GR-19441
GREECE

declare under our sole responsibility

that the products listed in the document

"**ML-PR-34014_MP-plus_Registration_Item List**"

are in conformity with the essential requirements and principles for safety and performance of the

Medical Devices Directive 93/42/EEC ("MDD") amended by Council Directive 2007/47/EC

are classified Class IIb according to the Annex IX, rule 11 of the above directive

are CE certified according to the conformity assessment route

Annex XI, Chapter I & Section 4, Full QMS and Technical Documentation

and supervision of the

Notified Body SGS Belgium NV (CE1639),
SGS House, Noorderlaan 87, 2030 Antwerp, Belgium

This declaration is signed electronically and valid until 2024-05-24,
the expiry date of the EC Full Quality Assurance System Certificate BG19/871877.