BIO GROUP – MEDICAL SYSTEM Srl
Strumentazione e Diagnostici
Loc. Campiano, 9/B – 47867 Talamello (RN)
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Digitally signed by Efremova Iulia
Date: 2024.12.16 11:41:05 EET
Reason: MoldSign Signature
Location: Moldova

Declaration of conformity certificate

We: Bio Group Medical System Srl Loc. Campiano 9/B, Talamello (RN) 47867 Italy
Ensure and declare with sole responsibility that the products:

Internal code: MSEQUALITYCH	Commercial name: QS Clinical Chemistry
EDMA Code: 38220000	First lot introduced in market: 112-NB
Internal code: MSEQUALITYPS	Commercial name: QS Specific Protein
EDMA Code: 38220000	First lot introduced in market: 220-NB
Internal code: MSEQUALITYEF	Commercial name: QS Electrophoresis
EDMA Code: 38220000	First lot introduced in market: 220-NB
Internal code: MSEQUALITYE8	Commercial name: QS Hematology
EDMA Code: 30021095	First lot introduced in market: 2020-EN
Internal code: MSEQUALITYC	Commercial name: QS Coagulation
EDMA Code: 38220000	First lot introduced in market: 084
Internal code: MSEQUALITYI	Commercial name: QS Immunology
EDMA Code: 38220000	First lot introduced in market: 360
Internal code: MSEQUALITYB	Commercial name: QS Bacteriology
EDMA Code: 38220000	First lot introduced in market: 326
Internal code: MSEQUALITYS	Commercial name: QS Serology
EDMA Code: 38220000	First lot introduced in market: 1020-SI
Internal code: MSEQUALITYU	Commercial name: QS Urine
EDMA Code: 38220000	First lot introduced in market: 002-U
Internal Code: MSEQUALITYH	Commercial name: QS HBA1C
EDMA Code: 38220000	First lot introduced in market: 001-H
Internal Code: MSEQUALITYD	Commercial name: QS Drug of Abuse
EDMA Code: 38220000	First lot introduced in market: 330-D
Internal Code: MSEQUALITYSO	Commercial name: QS FOB
EDMA Code: 38220000	First lot introduced in market: 110-F
Internal Code: MSEQUALITYESR	Commercial name: QS ESR
EDMA Code: 30021095	First lot introduced in market: 001-V
Internal Code: MSEQUALITYCM	Commercial Name: QS Cardiac Marker
EDMA Code: 38220000	First lot introduced in market: 201-C

meet the provisions of Council Directive 98/79/CE, annex I, as expected according to Council Directive 98/79/CE, annex III, concerning In Vitro Medical-Diagnostic Devices, which apply to us.
To this purpose, we guarantee and declare, on our own responsibility, what follows:

- Subsequent lots will be consistent with technical specification of the first lot. This conformity will be attested on the quality control certificate.
- The specified item satisfy the all dispositions applicable of Directive 98/79/CE
- We undertake in storing and placing to the competent Authority disposal the technical dossier of the product, as required by Council Directive 98/79/CE, annex III, as well as the production and control registrations for a period of at least 5 years after the last production date of the last lot.
- The specified device is designed, manufactured, and commercialized with date of first release not preceding the present one.

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The present conformity declaration has validity of a maximum of 5 years.

Moreover, the manufacturer declare to have established and to maintain an appropriate procedure to guarantee the post-sale surveillance, as requested by Council Directive 98/79/CE.

Talamello, 07/09/2020

The Executive Manager
Paolo Cocci