

CERTIFICATE

Number: 2155556

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Biochemical Systems International S.p.A

Localita Palazzo del Pero 23
52100 Arezzo
Italy

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

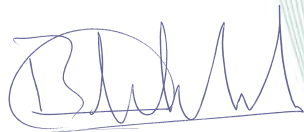
Scope:

The design and development, manufacture and service of in vitro diagnostic analyzers/software, reagents, test strips and control solutions, used in the detection and monitoring of blood analytes and blood components for near patient testing and self-testing.

Certificate expiry date: 1 March 2025
Certificate effective date: 8 March 2022
Certified since: 13 July 2012

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2155556

The management system of the organization(s) and/or location(s) of:

Biochemical Systems International S.p.A

Localita Palazzo del Pero 23
52100 Arezzo
Italy

Certified organization(s) and/or locations:

Different scope

Instrument Division Florence
Via Torta n70
50019 Sesto Fiorentino, Firenze
ITALY

The design and development, manufacture and service of in vitro diagnostic analyzers/software used in the detection and monitoring of blood analytes and blood components for near patient testing and self-testing.

Biochemical Systems S.p.A.
Galleria San Babila 4B
20122 Milano
Italy

Legal headquarter

Addendum expiry date: 1 March 2025
Addendum effective date: 8 March 2022