

CERTIFICATE

Number: 2155556

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

Biochemical Systems International S.p.A

Località 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, distribution and servicing of in vitro diagnostic analyzers/software, in vitro diagnostic reagents, test strips and control solutions used in the detection and monitoring of blood analytes and blood components including self-testing and near patient testing in-vitro diagnostic devices.

The distribution of lancets and lancing devices, continuous blood glucose monitoring systems and insulin pumps for the area of diabetes care.

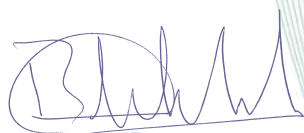
Certificate expiry date: 1 March 2028

Certificate effective date: 1 March 2025

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.M. McKenzie
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

Località Palazzo del Pero 23
52100 Arezzo
Italy

Certified organization(s) and/or locations:

Different scope

Instrument Division Florence
Via Torta n 70
50019 Sesto Fiorentino
Italy

The design and development, manufacture, distribution and servicing 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 International S.p.A. Legal headquarter
Galleria San Babila 4B
20122 Milano
Italy

Biochemical Systems International S.p.A. Warehouse
Via dei Frati 11/A
52100 Arezzo
Italy

Addendum expiry date: 1 March 2028
Addendum effective date: 1 March 2025