CERTIFICATE

Number: 2155556

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

Biochemical Systems International Srl

Località Palazzo del Pero 23 52100 Arezzo Italy

including the implementation meets the requirements of the standard:

ISO 13485:2003

Scope:

The design and development, manufacture, service of in vitro diagnostic analyzers/software, reagents, test strips and control solutions, including lancets and lancing devices used in the diagnosis and management of blood analytes and blood components including near patient // point of care and home use.

Certificate expiry date: 1 March 2019
Certificate effective date: 1 March 2016
Certified since: 13 July 2012

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

DEKRA Certification B.V.

drs. G.J. Zoetbrood Managing Director ing. A.A.M. Laan 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 Srl

Località Palazzo del Pero 23 52100 Arezzo Italy

Certified additional organization(s) and/or locations:
Organization/Location
Different scope

Instrument Division Florence Via B. Buozzi, 253 50013 Firenze The design and development, manufacture and service of in vitro diagnostic analyzers/software devices used in the diagnosis and management of blood analytes and blood components including near patient / point of care and home use

Biochemical Systems International Srl Località Palazzo del Pero 23 52100 Arezzo The design and development, manufacture, service of in vitro diagnostic analyzers/software, reagents, test strips and control solutions, including lancets and lancing devices used in the diagnosis and management of blood analytes and blood components including near patient / point of care and home use.

Addendum expiry date: // March 2019 Addendum effective date: // March 2016