

# 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: 215556

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
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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
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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.
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Addendum expiry date: 1 March 2019

Addendum effective date: 1 March 2016