CERTIFICATE

Number: 2161083

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

ELITechGroup S.p.A.

Corso Svizzera 185 10149 Torino Italy

including the implementation meets the requirements of the standard:

ISO 13485:2016 EN ISO 13485:2016

Scope:

The research and development, manufacture, distribution and servicing off/"in-vitro" diagnostic medical devices based on molecular biology methods.

The distribution and servicing of "in-vitro" diagnostic medical devices based on conventional methods.

Certificate expiry date: 7 January 2023 / Certificate effective date: 31 January 2020 Certified since: 1 October 2013

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: 2161083

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

ELITechGroup S.p.A.

Corso Svizzera 185 10149 Torino Italy

Certified organization(s) and/or locations:

Different scope

ELITechGroup S.p.A. Corso Svizzera 185 10149 Torino Italy

The research and development, manufacture, distribution and servicing off "in-vitro" diagnostic medical devices based on molecular biology methods.

The distribution and servicing of "in-vitro" diagnostic medical devices based on conventional methods

ELITechGroup S.p.A. Corso Italia 22 20122 Milano

Italy

Registered office without operational responsibilities

Addendum expiry date: 7 January 2023 Addendum effective date: 31 January 2020