

CERTIFICATE

Number: 2235223

The management system of:

ELITechGroup S.p.A.

Corso Svizzera 185
10149 Torino
Italy

Manufacturer DUNS 434528644

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009

Canada: Medical Devices Regulations - Part 1- SOR 98/282

United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

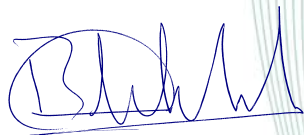
Design and development, manufacture, installation and service of in vitro diagnostic test kits, reagents and analyzers for detection of infectious, oncological and genetic disease markers by molecular biology methods

Certificate expiry date: 2023-01-07

Certificate effective date: 2020-01-31

Certified since: 2020-01-31

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

