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

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https:/www.dekra-product-safety.com/en/certified-organizations

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM