





Certificate

No. Q5 121998 0001 Rev. 00

Holder of Certificate: Nuclear Laser Medicine Srl

> Viale delle Industrie 3 20049 Settala MI **ITALY**

Certification Mark:



Scope of Certificate:

Design, development, production and sales of in vitro diagnostic reagents for genetic testing and infectious diseases. Design, development, production, installation and servicing of in vitro diagnostic software for nucleic acid testing. Distribution of in vitro diagnostic reagents and laboratory equipment for molecular genetics and microbiology applications and provision of laboratory equipment maintenance services.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 121998 0001 Rev. 00

Report No.: ITA2113833

Valid from: 2024-06-20 Valid until: 2027-06-19

2024-06-20

Christoph Dicks

Head of Certification/Notified Body

Date,





Certificate

No. Q5 121998 0001 Rev. 00

ISO 13485:2016 Applied Standard(s):

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): **Nuclear Laser Medicine Srl**

Viale delle Industrie 3, 20049 Settala MI, ITALY

Design, development, production and sales of in vitro diagnostic reagents for genetic testing and infectious diseases. Design, development, production, installation and servicing of in vitro diagnostic software for nucleic acid testing. Distribution of in vitro diagnostic reagents and laboratory equipment for molecular genetics and microbiology applications and provision of laboratory

equipment maintenance services.

Nuclear Laser Medicine Srl

Via Cascina Conighetto sn, 20049 Settala (Mi), ITALY

Representative company address for Nuclear Laser Medicine Srl

١