CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

Vitroscreen S.r.I.

-VitroScreen

Via Mosè Bianchi 103

IT - 20149 Milano (MI)

has established and applies a quality management system for the following scope:

Design and development of in vitro preclinical studies for the assessment of the safety, efficacy, mechanism of action and ADME for medical devices. Provision of consulting services for the evaluation of the toxicological profile and biocompatibility assessment for medical devices.

Through an Audit, Report No. 7981113040DS26, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2021

Please refer to the Quality Manual for the details about the exclusions with respect to the requirements of the standard.

Certificate Registration No. 39 05 0822206.

This Certificate is valid from 2023-03-22 to 2026-03-21.

The reference date for all the next audits is (day-month): 27-01.

Milan, 2023-03-22. First Certification: 2023-03-22

The certification responsible: Lisa Menarini

TÜV Rheinland Italia S.r.I., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC, 90/385/EEC, 98/79/EC or Regulations (UE) 2017/745, (UE) 2017/746 have been fulfilled



SGQ N° 083A SGA N° 052

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreement



Management System EN ISO 13485:2016

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