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Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021

Registration No.: SX 2333085-1

Certificate Holder: Dia.Metra Srl

Via Pozzuolo 14 06038 Spello (PG)

Italy

Scope: Design and development, manufacture and distribution

of in vitro diagnostic kits to be used as an aid to diagnosis and/or monitoring of disorders related to thyroid function and stimulation hormones, fertility and pregnancy function hormones and proteins, diabetes hormones, renal metabolism,

anemia, autoimmune connective tissue, markers

for autoimmune thyropathies, vasculitis, anti-phospholipid syndrome, coeliac, rheumatoid and inflammatory, tumor markers, complement components, peptides and endocrine hormones, allergy, immunoglobulin, autoimmune thyropathies,

bone and mineral metabolism.

Distribution of molecular biology in vitro diagnostic kits.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

 Report No.:
 84981243-30

 Effective date:
 2025-06-09

 Expiry date:
 2028-06-08

 Issue date:
 2025-06-04

Replaces certificate SX 2333085-1 issued 2023-02-15

This certificate can be validated on https://www.certipedia.com

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