CERTIFICATE

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

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

PRO DATA S.r.I.

Via Luigi Einaudi, 198 IT - 63821 Porto Sant'Elpidio (FM)

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

Design, manufacture, installation and support of computer systems for the management and reporting of diagnostic images and clinical data. Placing on the market and support of software and hardware for medical use.

Through an Audit, Report No. 7981309010AF19, 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 12211506.

This Certificate is valid from 2022-10-11 to 2025-10-10.

The reference date for all the next audits is (day-month): 19-06.

Milan, 2022-10-11. First Certification: 2013-10-11

The certification responsible: Daniele Ricchi

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° 083 A





Management System EN ISO 13485:2016





