C E R T I F I C A T E

Management System as per
ISO 13485 : 2016

The Certification Body TÜV NORD Brasil hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2016, that the organization

S.R. Productos Para La salud S.A.
Calle Saldanha Rodrigues, 1855, Ruta PY05 Km 3
Pedro Juan Caballero - Amambay
Paraguai

operates a management system in accordance with the requirements of ISO 13485 : 2016 and will be assessed for conformity within the 3 years term of validity of the certificate.

Scope

Manufacture and sale of hypodermic syringes and syringes for enteral nutrition, sterile single-use syringes for manual use, sterile single-use hypodermic needles, universal collectors, safety devices for syringes and hypodermic needles, single-use oral doser, plastic film for blister, single-use enteral nutrition bottles and TPE-S/SR thermoplastic elastomer rubber resin.

Certificate Registration No. TNBR-28633
Audit Report - WO 23316

End of validity of the previous certificate: 2025-03-14
Valid from 2025-04-14
Valid until 2028-03-14
Initial Certification 2013

Reynaldo Serra
Director

Barueri, 2025-04-14

The validity of this certificate is subject to the continuous and satisfactory compliance of the company to the conditions stated in the certification contract.

Gestão de Produtos para Saúde
OMD 0002