



CERTIFICATE

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 - Amabay
Paraguay

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 commercialization of single-use sterile hypodermic syringes for manual use, single-use sterile hypodermic needles, universal collectors, safety devices for syringes and hypodermic needles, single-use oral doser, plastic film for blisters, bottles for enteral nutrition for singleuse, thermoplastic elastometer rubber resin TPE-S/SR and disposable diaper for adult use.

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


Certification Body
TÜV NORD Brasil



Barueri, 2026-05-19

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

TÜV NORD Brasil Avaliações da Qualidade Ltda. Al. Madeira, 222 – 3º Andar – 06454-010 – Barueri – SP tuv-nord.com/br



Revisão	Data	Descrição
00	14/04/2025	Emissão inicial
01	19/05/2026	Alteração do escopo