



# MDSAP CONFORMITY CERTIFICATE

FNCC\_680 Rev. 09

Página 1 de 2

Certificate No. NCC 25.11325.01

Certificate valid only accompanied of pages 1 through

Certificado de Conformidade válido somente acompanhado das páginas de 1 a 2

Effective Date: 2025-03-13

Expiry Date: 2028-03-12

NCC Certificações do Brasil Ltda., an MDSAP authorized Auditing Organization, certifies that the Quality Management System of:

**EXO S.A.**

**Data of the Organization:**

**Address:** Avenida Chiclana, nº 3444, C1260ACO, Buenos Aires - Argentina

**CNPJ:** N/A

**Facility's identification number - (REPs):** F005999

has been found to conform to the Quality Management System Standard

**ISO 13485:2016**

**Brazil:**

RDC ANVISA nº 665/2022

RDC ANVISA nº 551/2021

RDC ANVISA nº 67/2009

**Canada:**

Medical Devices Regulations – Part 1- SOR 98/282

Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)

**USA:**

21 CFR Part 803 - Medical Device Reporting

21 CFR Part 806 - Reports of Corrections and Removals

21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing

21 CFR Part 820 - Quality System Regulation

**Scope:** "Design, development, manufacturing, importing, sales and post-marketing supporting of monitoring and diagnostic medical devices"

**Not applicable items:**

- 7.5.3: Installation activities
- 7.5.5: Particular requirements to sterile medical devices.
- 7.5.6: Validation of production processes and service provision.
- 7.5.7: Particular requirements to process validation of sterilization and sterile barrier system.
- 7.5.9.2: Particular requirements to implantable.
- 7.5.10: Customer property.



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*Further clarifications regarding this certificate, such as: revision, expiry date, scope description, standards and status, may be obtained by consulting the NCC/BV site <https://www.nccgroup.com.br/atuacao/mdsap/certificados-emitidos-mdsap/>.*

*Further clarifications regarding the scope of this certificate and the applicability of MDSAP Requirements may be obtained by Consulting the Organization.*

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Wilson Bonato  
Technical Manager

## Certification History

Revision	Certificate	Date of issue	Process	Description
00	NCC 25.11325	2025-03-13	61882/20.1.Re1	Recertification of NCC 22.07131 certificate
01	NCC 25.11325	2025-04-28	61882/20.1.Re1	Correction in certificate expiration date

