



Certificate

— of Registration

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

EXO S.A.

Data of the Organization:

Address: Av. Chiclana, nº 3444, C1260 ACO, 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

Brasil: RDC ANVISA nº 16/2013; RDC ANVISA nº 23/2012; RDC ANVISA nº67/2009

EUA: 21 CFR 820

Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68; Japan PMD Act (as applicable)

Canada: Medical Device Regulations SOR/98-282, Part 1

Australia: Schedule 3, Part 1 - Full Quality Assurance System; Schedule 3, Part 4 - Production Quality Assurance Procedures

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.

The quality management system of the manufacturer listed on the certification document has been audited against stated criteria and found to conform to those criteria for the scope contained in the certification document.

Certificate Number: NCC 22.07131

Revision nº.: 00

Certification Effective: 2022-03-11

Certification Expiry: 2025-03-11

Verification: It's possible to find the information of the validity of this certificate in NCC's web site:
<http://www.nccgroup.com.br>

Certification History

Rev.	Certificate	Date	Description
00	NCC 22.07131	2022-03-11	Initial issue

Wilson Bonato
Technical Manager

Identificação interna do documento O5E9XLRJY2-G5UZV8P2



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