CERTIFICATE

Number: 3825428

The management system of:

Next Science, LLC

10550 Deerwood Park Blvd, Suite 300 Jacksonville, FL 32256 United States Of America

Manufacturer Facility Identifier F002932

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1

(excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA N 16/2013, 23/2012 and 67/2009 Canada: Medical Devices Regulations - Part 1- SOR 98/282

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Supports A to D and 21 CFR 820

Scope:

Design, development, and manufacture of sterile and non-sterile wound care devices and lavages including those with medicinal component for the area of interventional medicine

Certificate expiry date: 8 July 2025
Certificate effective date: 8 July 2022
Certified since: 8 July 2019

DEKRA Certification B.V

B.T.M. Holtus Managing Director J.A. van Vugt

Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link: https://www.dekra-product-safety.com/en/certified-organizations

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

