MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000474330-PA-NA-DNK

Initial certification date:
22 July 2021

Valid:
19 February 2022 – 18 August 2024

This is to certify that the management system of

NidaCon International AB

Flöjelbergsgatan 16B, 431 37, Mölndal, Västergötland, Sweden

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, development, manufacture, sales and marketing of medical devices for ART (Assisted Reproduction Technology).

Digitally signed by Bolea Petru
Date: 2023.06.07 15:22:51 EEST
Reason: MoldSign Signature
Location: Moldova

Place and date:
Høvik, 18 February 2022

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

2023-02-15 Diarienummer: 6.6.1-2023-014541

Registreringsbekräftelse / Confirmation of registration

Företagsnamn / Company name:	Nidacon International AB
Organisationsnummer / Company registration number:	556548-2329
Utdelningsadress / Address:	Flöjelbergsgatan 16B 43137 Mölndal Sverige
Eudamed-registreringsnummer / SRN:	SE-MF-000001933

Registrering enligt förordning (EU) 2017/745 (MDR) om medicintekniska produkter, förordning (EU) 2017/746 (IVDR) om medicintekniska produkter för in vitro-diagnostik, Läkemedelsverkets föreskrifter (HSLF-FS 2021:32) om informations- och rapporteringsskyldighet avseende medicintekniska produkter och/eller Läkemedelsverkets föreskrifter (LVFS 2001:7) om medicintekniska produkter för in vitro-diagnostik

Nidacon International AB intygar i och med att de registrerar sin verksamhet hos Läkemedelsverket att de fullgör sina skyldigheter i enlighet med tillämpliga krav i gällande förordning(ar)/föreskrift(er).

Registreringen avser roll: Tillverkare av CE-märkta produkter

Registration according to Regulation (EU) 2017/745 (MDR) on medical devices, Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices, the Swedish Medical Products Agency's Regulations (HSLF-FS 2021:32) on information and reporting requirements regarding medical devices and/or the Swedish Medical Products Agency's Regulations (LVFS 2001:7) on in vitro diagnostic medical devices

Nidacon International AB declares by registering their business at the Swedish Medical Products Agency that they fulfil their obligations in accordance with applicable requirements in existing Regulation(s).

The registration relates to actor role: Manufacturer of CE marked devices

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0) 18 17 46 00 Fax: +46 (0) 18 50 31 15
Webbplats: www.lakemedelsverket.se E-post: registrator@lakemedelsverket.se

CE-märkta produkter / CE marked devices

Produktkategori / Category	Riskklass / Risk class	Antal produkter / Number of devices
U: Medical devices, urogenital apparatus	MDD klass IIa	3
U: Medical devices, urogenital apparatus	MDD klass IIb	9
V: Medical devices - various	MDD klass III	1
W: In vitro diagnostic devices (d. Lgs. 332/2000)	IVDD generell	1
Z: Medical equipment and related accessories and materials	MDR klass I	2

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