

CERTIFICATE OF CONFORMITY

Directive 93/42/EEC on MEDICAL DEVICES, Annex IV
Devices in Class IIb

The certificate : 18M00056CRT01

issued by: **DARE!! Medical Certifications**
Vijzelmolenlaan 7
3447 GX Woerden
The Netherlands

to:
Manufacturer : Nemo Healthcare B.V.
Address : De Run 4630 "MMC Incubator"
5504 DB Veldhoven
The Netherlands

Authorised Representative (EAR) : Not applicable
Address : Not applicable

regarding the product(s):
Type : Nemo Fetal Monitoring System (NFMS), consisting of:
Nemo patch ATLPAT01, Nemo Base ATLBAS01, Nemo Link ATLLNK01
Brand name : --
Identification : P002301 (base station), P002300 (links), 040084 (patches). See annex.
Batch size : 24 bases with 48 headboxes and 2000 patches

and grants the right to use the EC Notified Body Identification Number as represented below to accompany the CE Marking on the product(s) concerned in conformance with the required Technical Documentation and meeting the provisions of the EC Directive which apply to these product(s).

1912

This certificate is based on the following documents:

- 18M00029CRT02
- 18M00056RPT01

DARE!! Medical Certifications hereby declares that an examination on the product(s) according to Annex IV, section 4 is conducted, that the batch of products is conform the type described in the EC Type-Examination certificate and the relevant provisions of the Directive 93/42/EEC dated June 14, 1993 concerning Medical Devices, including all subsequent amendments and transposed into Dutch legislation under the name "Besluit Medische Hulpmiddelen" are fulfilled.

Issued: **31-10-2018**

DARE!! Medical Certifications



D. van der Vlugt
Certification decision maker / Director

Certificate number: 18M00056CRT01



DARE!! Medical Certifications

Medical certification services

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Annex to CERTIFICATE OF CONFORMITY

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Overview of serial numbers

Serial no. Base station	Serial no. Links
002301001	002300002, 002300001
002301008	002300015, 002300016
002301009	002300017, 002300018
002301007	002300013, 002300014
002301006	002300011, 002300012
002301004	002300007, 002300008
002301005	002300009, 002300010
002301002	002300003, 002300004
002301003	002300005, 002300006
002301017	002300033, 002300034
002301016	002300031, 002300032
002301015	002300029, 002300030
002301014	002300027, 002300028
002301013	002300025, 002300026
002301012	002300023, 002300024
002301010	002300019, 002300020
002301011	002300021, 002300022
002301020	002300039, 002300040
002301023	002300045, 002300046
002301019	002300037, 002300038
002301018	002300035, 002300036
002301026	002300051, 002300052
002301024	002300047, 002300048
002301025	002300049, 002300050

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