

MDD - Product List

Products included in the Certificate No:

Issued to:

41319283

NeoDynamics AB

Lejonvägen 14, 181 32 Lidingö SWEDEN

| Product category | Type/Model designation | Class | Sterile | GMDN code (not mandatory) | Date added |
|--|--|-------|---------|---------------------------------|---------------|
| Biopsy system (for breast lesions and axillary lymph nodes for diagnostic analysis) | NeoNavia Base Unit REF#1101 | lla | No | | 12 July, 2016 |
| | NeoNavia Base Unit REF #1102 | lla | No | | 24 Oct 2019 |
| | NeoNavia Driver REF#1103 | lla | No | | 24 Oct 2019 |
| Biopsy system accessories | NeoNavia Biopsy Device REF#2101 | lla | Yes | | 12 July, 2016 |
| | NeoNavia VacuPulse probe REF#2102 | lla | Yes | | 24 Oct 2019 |
| | NeoNavia Core Pulse probe REF#2103 | lla | Yes | | 24 Oct 2019 |
| | NeoNavia FlexiPulse probe REF#2104 | lla | Yes | | 24 Oct 2019 |

Date of Issue: October 24, 2019

Intertek Semko AB Notified Body MDD

Peter Nermander

Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

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