# EC Certificate

## FULL QUALITY ASSURANCE SYSTEM
## Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

**Certificate Number**
**41319283**

**Initial Certification Date**
**July 12, 2016**

**Certificate Valid from**
**July 12, 2016**

**Certificate Expiry Date**
**July 11, 2021**

*The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.*

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

*Intertek Semko AB*
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Ackred. nr 1003
ISO/IEC 17021

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

**Organization:**

## NeoDynamics AB

Lejonvägen 14, SE - 181 32 Lidingö, Sweden

**Product Category:**

Biopsy system (for breast lesions and axillary lymph nodes for diagnostic analysis)

For further identification of the products covered, see the MDD product list/product schedule.

July 12, 2016
Signed date

Mats Premfors, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

2015-09-30

# MDD – Product List

Products included in the Certificate No: 41319283
Issued to: **NeoDynamics AB**
Lejonvägen 14,
181 32 Lidingö
SWEDEN

| Product category | Type/Model designation | Class | Measuring | GMDN code (not mandatory) | Date added |
|---|---|---|---|---|---|
| Biopsy system (for breast lesions and axillary lymph nodes for diagnostic analysis) | NeoNavia Base Unit REF#1101 | IIa | No | | 12 July, 2016 |
| | NeoNavia Biopsy Device REF#2101 | IIa | No | | 12 July, 2016 |

Date of Issue: July 12, 2016

**Intertek Semko AB**
Notified Body MDD

Mats Premfors
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.

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