

# EC CERTIFICATION

## FULL QUALITY ASSURANCE SYSTEM

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

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:**

## Progressus Medica AB

Main Site: Fornuddsvägen 109, SE-135 52 Tyresö, Sweden

**Product Category:**

- Therapeutic X-ray equipment

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

**Certificate Number:**

41317498-01

**Initial Certification Date:**

15 March 2010

**Certificate Valid from:**

11 September 2020

**Certificate Expiry Date:**

26 May 2024



Accred. no. 1003  
Certification of  
Management  
Systems  
ISO/IEC 17021-1

**Mikael Hagelin**

Certification Authority MDD  
Intertek Semko AB, Kista, Sweden

11 September 2020

**Signed Date**

Intertek Semko AB  
Box 1103, SE-164 22 Kista, Sweden  
Telephone +46 8 750 00 00  
medtechsweden@intertek.com

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.



Products included in the Certificate No: 41317498-01  
Issued to: **Progressus Medica AB**  
Fornuddsvägen 109  
SE-135 52 Tyresö  
Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
Therapeutic X-ray equipment	Grenz Ray	Ib	No		March 15, 2010

Valid date: 11 September 2020

**Intertek Semko AB**  
Notified Body MDD



Mikael Hagelin  
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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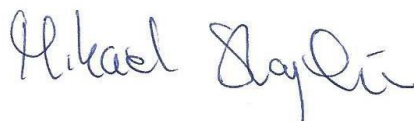
Certificate No: 41317498-01  
Date: 11 September 2020  
Handled by: Caroline Åman  
E-mail: medtechsweden@intertek.com

**Progressus Medica AB**

Attn: Bernt Lindelöf  
Fornuddsvägen 109  
SE-135 52 Tyresö  
Sweden

<b>Purpose</b>	Assessment to issue a new certificate due to five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
<b>Activity</b>	Certification audit was performed 5 September 2019 in Tyresö by Göran Nerby. The technical file was reviewed 10 September 2020 by Gustav Sundström at Intertek's office.
<b>Scope of assessment</b>	Therapeutic X-ray equipment, Class IIb
<b>Result</b>	5 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
<b>Certificate Valid from</b>	11 September 2020
<b>Conclusions/Decisions</b>	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II will be issued. The Certificate is valid for products specified in the "MDD – Product List".
<b>Follow-up assessments</b>	Follow-up assessments are going to be performed once a year.
<b>Appeals</b>	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
<b>Others</b>	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

**Intertek Semko AB**  
Notified Body MDD



Mikael Hagelin  
Certification Authority MDD