eurofins

## QUALITY MANAGEMENT SYSTEM

# EU-CERTIFICATE

## Regulation (EU) 2017/745

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|---|---|
| Manufacturer: | PaloDEx Group Oy<br>Nahkelantie 160<br>FI-04300 Tuusula<br>Finland |
| Single registration number: | FI-MF-000004943 |
| Conformity assessment procedure: | Regulation (EU) 2017/745 Annex IX |
| Device category: | MDA 0201 Active non-implantable imaging devices utilising ionizing radiation |
| Date of expiry: | 6 March 2028 |

The manufacturer's quality management system covering the device category has been assessed and approved in accordance with the Annex IX to Regulation (EU) 2017/745. Approval shall be valid until the expiry date provided that the manufacturer fulfills the obligations imposed by Annex IX in Regulation. The products covered by the certificate and the details related to the maintenance of this certificate are specified in the attachment(s) to the certificate.

Date of issue: 6 March 2023

Aliina Nieminen

Satu Rajala

Certificate no:

**CR-03-1154-812-23**

Notified Body no. 0537:
Eurofins Electric & Electronics Finland Oy
Kivimiehentie 4
FI-02151 Espoo, FINLAND

Information about the examinations and tests as per MDR Annex XII, section 10, is available upon request from EES-medical@eurofins.fi.

# Attachment 1 to the certificate no: CR-03-1154-812-23

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| **Manufacturer:** | PaloDEx Group Oy<br>Nahkelantie 160<br>FI-04300 Tuusula<br>Finland |
| **Other sites covered by the quality management system:** | - |
| **Single registration number:** | FI-MF-000004943 |
| **Conformity assessment procedure:** | Regulation (EU) 2017/745 Annex IX |
| **Limitations to the validity of the certificate:** | No limitations |

**The certificate covers the following products:**

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| **MD-codes:** | MDA 0201<br>MDS 1009<br>MDT 2010, 2011, 2012 | |
| **Device category:** | MDA 0201 Active non-implantable imaging devices utilising ionizing radiation | |
| **Generic device group:** | Z110305 | |
| *Product name* | *Product details* | |
| ORTHOPANTOMOGRAPH ™ OP 3D | Model | PCX-1 |
| | Nomenclature code | Z11030507 TOMOGRAPHS |
| | Risk class | IIb |
| | Intended purpose | ORTHOPANTOMOGRAPH™ OP 3D is an x-ray device that is intended to be used for imaging of adult and pediatric patients. The device can be configured to take panoramic, cephalometric, or 3D images of the cranio-maxillofacial complex for use in diagnostic support. The device can also be configured to take carpus images. The device is operated and used by qualified healthcare professionals. |
| ORTHOPANTOMOGRAPH ™ OP 3D LX | Model | PCX-1 |
| | Nomenclature code | Z11030507 TOMOGRAPHS |
| | Risk class | IIb |
| | Intended purpose | ORTHOPANTOMOGRAPH™ OP 3D LX is an X-ray device that is intended to be used for imaging of |

## Attachment 1 to the certificate no: CR-03-1154-812-23

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| | | adult and pediatric patients. The device can be configured to take panoramic, cephalometric or 3D images of cranio-maxillofacial complex including the ear, nose and throat (ENT) and airway regions, and cervical spine. The device can be configured to take carpus images. The device is operated and used by qualified healthcare professionals. |
| ORTHOPANTOMOGRAPH ™ OP 3D EX | Model | PCX-1 |
| | Nomenclature code | Z11030507 TOMOGRAPHS |
| | Risk class | IIb |
| | Intended purpose | ORTHOPANTOMOGRAPH OP 3D EX is an X-ray device that is intended to be used for imaging of adult and pediatric patients. The device can be configured to take panoramic or 3D images of craniomaxillofacial complex including the ear, nose and throat (ENT) and airway regions, and cervical spine. The device is operated and used by qualified healthcare professionals. |

The validity and maintenance of this certificate require the surveillance performed by the notified body in accordance with the MDR Annex IX (3). The surveillance includes annual quality management system audits at the manufacturer's premises as well as regular unannounced audits. If necessary, all audits may be carried out at the premises of the manufacturer's suppliers and/or subcontractors. The surveillance also includes the assessment of the significant changes planned by the manufacturer and the assessment of the technical documentation in accordance with the notified body's sampling plan (IIa and IIb).

Date of issue of this attachment: 17 May 2024

Aliina Nieminen Satu Rajala

This attachment 1 supersedes the previous attachment 1 issued 10 March 2023.

# Attachment 1 to the certificate no: CR-03-1154-812-23

| Change history of the certificate: | | | | |
|---|---|---|---|---|
| **Certificate no** | **Revision** | **Status of the certificate** | **Date of issue** | **Description of the change** |
| CR-03-1154-812-23 | 01 | Initial certification | 6.3.2023 | Initial revision. |
| CR-03-1154-812-23 | 02 | Supplemented | 10.3.2023 | Adding a new product ORTHOPANTOMOGRAPH™ OP 3D LX to the EC certificate based on NB-1154-M23. |
| CR-03-1154-812-23 | 03 | Supplemented | 17.5.2024 | Adding a new product ORTHOPANTOMOGRAPH™ OP 3D EX to the EC certificate based on NB-1154-M24. |
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