

EC Certificate Full Quality Assurance System: Certificate BE19/819943459

The management system of

Barco N.V. Healthcare Division

Beneluxpark 21
8500 Kortrijk, Belgium

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 05 February 2021 until 22 January 2023
and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 15 January 2007

Certification is based on reports numbered BE/AND 213255

This is a multi-site certification.
Additional site details are listed on subsequent pages

Authorised by



Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Barco N.V. Healthcare Division

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

Diagnostic radiology and mammography display devices and associated display processing software.
Diagnostic pathology display devices.
Intuitive Workflow Tools (IWT): stand-alone software package as accessory for diagnostic radiology and mammography display devices intended for the enhancement of radiology and mammography images.
QAWeb Enterprise: stand-alone quality assurance software as accessory for medical imaging displays.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

President Kennedypark 35, Kortrijk, 8500, Belgium

Noordlaan 3, Kuurne, 8520, Belgium



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Beneluxpark 21
8500 Kortrijk, Belgium

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This corrigendum is only valid together with accompanying 93/42/EEC certificate Issue 6

<u>Correction Date</u>	<u>Correction</u>
Change approved by SGS on 01 July 2021	Correction of address: the registered place of business is 'President Kennedypark 35, 8500 Kortrijk, Belgium'. The address 'Beneluxpark 21, 8500 Kortrijk, Belgium' is listed as additional facility.

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LPMD5105 – Corrigendum to Certificate

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SGS Belgium NV

Certification and Business Enhancement Maatschappelijke Zetel/Siège Social:
Noorderlaan 87 B-2030 Antwerpen/Anvers
t +32 (0)3 545 48 48 f +32 (0)3 545 48 49
www.be.sgs.com

Member of the SGS Group