FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS (FAMHP)

FREE SALE CERTIFICATE

Medical devices (MD)

N° of Certificate: 000009 04-11-21

Exporting (certifying) country: **Belgium**

Importing (requesting) country: Vietnam

SECTION TO BE COMPLETED BY THE APPLICANT OF THE CERTIFICATE

1. Name and form of product:

For class I, system and procedure pack and custom made MD, please provide the notification number

Digitizer

1.1. Grouping according to Directive 93/42/EC: ○ I ○ Is/Im ○ I + Is/Im ◉ IIa ○ IIb ○ III

○ System and procedure pack ○ Custom made

1.2. Qualitative and quantitative composition or description (according to the type of the device):

The qualitative and quantitative compositions are indispensable if the device is in the form of a solution, cream, gel .....

- CR 10-X: The CR 10-X is part of a CR system, further containing a cassette, image plate and modality workstation. The CR system is used in a radiological environment by qualified staff to read-out, process and route static X-ray radiographic images. The cassette is used to protect the image plate from light and damages during X-ray exposure, transport and handling. The image plate is used to capture the static X-ray radiographic images; the image plate is scanned by the digitizer. The CR 10-X digitizer is used to scan an X-ray exposed image plate; it results into a digital image which is sent to the dedicated workstation. The modality workstation is used to process and route the digital images from the digitizer.
- CR 12-X: The CR 12-X is part of a CR system, further containing a cassette, image plate and modality workstation. The CR system is used in a radiological environment by qualified staff to read-out, process and route static X-ray radiographic images. The cassette is used to protect the image plate from light and damages during X-ray exposure, transport and handling. The image plate is used to capture the static X-ray radiographic images; the image plate is scanned by the digitizer. The CR 12-X digitizer is used to scan an X-ray exposed image plate; it results into a digital image which is sent to the dedicated workstation. The modality workstation is used to process and route the digital images from the digitizer.
- CR 15-X: The CR 15-X is part of a CR system, further containing a cassette, image plate and modality workstation. The CR system is used in a radiological environment by qualified staff to read-out, process and route static X-ray radiographic images. The cassette is used to protect the image plate from light and damages during X-ray exposure, transport and handling. The image plate is used to capture the static X-ray radiographic images; the image plate is scanned by the digitizer. The CR 15-X digitizer is used to scan an X-ray exposed image plate; it results into a digital image which is sent to the dedicated workstation. The modality workstation is used to process and route the digital images from the digitizer.
- CR30-Xm: CR30-Xm is a compact device to read and display medical images captured on a photo-stimulable screen.
- DX-M: The DX-M digitizer unites superb image quality with a drop-and-go buffer-based workflow and enables a potential reduction in patient dose. It offers the unprecedented convenience of being able to combine standard phosphor plates and needle-based detectors. The DX-M can be used as a centralized or decentralized digitizer in the radiography department, supporting digital mammography and general radiography. In a centralized environment, it can serve multiple rooms. At the same time, its small footprint means it can be placed in any available space.

1.3. Does the product contain animal substances? No

If yes, which animal substance?

1.4. Does the product contain medicinal substances? No

If yes, which medicinal substance?

1.5. Does the product contain radioactive substances? No

If yes, which radioisotope and how much Becquerel?

1.6. Is this product authorized to be placed on the market for use in the exporting country? Yes

1.7. Is this product actually on the market in the exporting country? Yes

1.8. Does the exported product carry the CE mark according to Directive 93/42/EC? Yes

2. Information regarding the manufacturer:

2.1. Manufacturer (according to the definition of Directive 93/42/EC): name and address:

Agfa NV, Septestraat 27, 2640 Mortsel, Belgium

2.2. Applicant for certificate:

Wim Govaerts, Agfa NV, Septestraat 27, 2640 Mortsel, Belgium

2.3. Name and number of the Notified Body (if applicable): Intertek Semko AB, id number 0413

2.4. Has the manufacturer been certified to be in compliance with ISO 9000/ EN 13485 standards? Yes

If yes state the name of the organisation that delivered the certificate: Intertek Medical Notified Body AB

If no, please explain:

RESERVED FOR THE ADMINISTRATION

The medical device as described above is presumed to meet the applicable provisions of Council Directive 93/42/EEC and can be placed on the market in the exporting country.

Address of certifying authority:	FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS Avenue Galilée, 5/03, 1210 BRUSSELS (BELGIUM) Telephone n°: +32 2 528.40.00
Date: 04/11/2021	Name of authorized person:
Stamp:	Xavier De Cuyper Chief Executive Officer P.O. Hugues MALONNE Directeur général - DG-POST Hugues Malonne (Authentication) Digitally signed by: Hugues Malonne (Authentication) DN: CN = Hugues Malonne (Authentication) C = BE Date: 2021.11.05 17:21:37 +01'00'

ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI BỈ
EMBASSY OF THE S.R OF VIETNAM IN BELGIUM

CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia **VIỆT NAM**
Country *Vietnam*

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà) ..... **Veldeman Martine** ..... **ký**
has been signed by

3. với chức danh ..... **Viên chức lãnh sự** .....
Acting in the capacity of: Consular Officer

4. và con dấu của ..... **Bộ Ngoại giao Vương quốc Bỉ** .....
bears the seal/stamp of

.....

được chứng nhận/hợp pháp hóa lãnh sự
Certified

5. tại **Brúc-xen** **6. ngày 24 / 11 / 2021**
at *the*

7. Cơ quan cấp ĐSQ CHXHCN VIỆT NAM TẠI BỈ
by

8. Số 963/2021 - CNLS/HPHLS
N°

TL. Đại sứ/ For the Ambassador
Bí thư thứ Ba/Third Secretary

Trương Ngọc Thang

ĐẠI SỨ QUÁN CHXHCN VIỆT NAM TẠI BỈ

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LEGALISATIE - LEGALISATION - LEGALISATION

Gezien voor de legalisatie van de handtekening van :
Vu pour légalisation de la signature de :
Gesehen zur Legalisation der Unterschrift von :
Malonne Hugues

Onder Nr./Sous le n°/Unter Nr. : ***211118221698***

Te/A/In : ***Brussel/Bruxelles/Brüssel*** Op/Le/Am : ***15/11/2021***

Stempel/Sceau/Stempel: Ondertekening/Signature/Unterschrift:

Veldeman Martine

Document/Document/Dokument ***Attest/certificaat/Attestation/certificat/Bescheinigung***

Prijs/Prix/Preis: ***20*** EUR

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https://legalweb.diplomatie.be

AGFA

Production Site Declaration

The following devices:

- CR 10-X
- CR 12-X
- CR 15-X

are produced at the site of:

- Agfa (Wuxi) Imaging Co., Ltd. No.1 Workshop, 115# Plot, National Hi-Tech Industrial Development Zone Wuxi, Jiangsu, 214028 China

- Agfa-Gevaert HealthCare GmbH, Max-Planck-Str. 1, 82380 Peissenberg, Germany

On behalf of Agfa NV, Septestraat 27, 2640 Mortsel, Belgium

Production Site Declaration

The following devices:

- CR30-Xm
- DX-M

are produced at the site of:

Agfa-Gevaert HealthCare GmbH, Max-Planck-Str.1, 82380 Peißenberg, Germany.

On behalf of Agfa NV, Septestraat 27, 2640 Mortsel, Belgium