Belgian Federal Public Service (FPS): HEALTH, FOOD CHAIN SAFETY and ENVIRONMENT, Directorate General - Medicinal Products

FREE TRADE CERTIFICATE OF A MEDICAL DEVICE

N° of Certificate : 2006 / 09 / 20 / 035
Exporting (certifying) country : **Belgium**
Importing (requesting) country : **Vietnam**

SECTION TO BE COMPLETED BY THE APPLICANT OF THE CERTIFICATE

1. Name and form of product: Printers, video
1.1. Classification according to Council Directive 93/42/EEC : I
1.2. Qualitative and quantitative composition or description (according to the type of the device):
The product is marketed under different names and types :
- **DRYSTAR 4500M :** High resolution (508 dpi), high throughput thermal printer for black and white images of size 8"x10" or 10"x12" dedicated for printing digital mammographic images.
- **DRYSTAR 5300 :** Dry Thermal printer for black and white medical images of size 11"x14" or 14"x17" with a resolution of 320 dpi.
- **DRYSTAR 5302 :** Dry Thermal printer for black and white medical images of size 8"x10", 10"x12", 11"x14", 14"x14" or 14"x17", two on-line sizes with a resolution of 320 dpi.
- **DRYSTAR 5503 :** Drystar 5503 is a high-throughput, high-resolution (508 dpi), multiple media size direct digital imager for black and white medical images.

1.3. Is this product authorized to be placed on the market for use in the exporting country? **YES**
1.4. Is this product actually on the market in the exporting country? **YES**
1.5. Does the exported product carry the CE mark according directive EEC/93/42? **YES**

2. Information regarding the manufacturer:
2.1. Manufacturer (according to the definition of Council Directive 93/42/EEC):**AGFA-GEVAERT N.V., Septestraat 27, B-2640 Mortsel, Belgium**
2.2. Production site: **Agfa-Gevaert HealthCare GmbH, Max-Planck-Str.1, D-82380 Peißenberg, Germany**
2.3. Applicant for certificate : **Jan Langmans, AGFA-GEVAERT N.V., Septestraat 27, B-2640 Mortsel, Belgium**
2.4. Name and number of the Notified Body (if applicable) : **N/A for class I product**

3. Has the production facility been certified to be in compliance with ISO 9000 / ISO 13485 standards ? **YES**
If yes state the name of the organisation that delivered the certificate : **Lloyd's Registered Quality Assurance**
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:	Belgian Federal Public Service (FPS): HEALTH, FOOD CHAIN SAFETY and ENVIRONMENT, Directorate General for Medicinal Products, EUROSTATION, Bloc 2, Office 8D11, Victor Hortaplein 40 bus 10, 1060 BRUSSELS (BELGIUM)
Telephone n°: 32 2 524.82.97	Fax n°:32 2 524.83.01
Stamp and date: Attest getaxeerd overeenkomstig art. 4 § 2 van het K.B. van 01/09/2000 ten bedrage van 50.00 EUR, ingeschreven voor ontvangst op 20. 09. 2006	Name of authorized person: Johan VAN CALSTER, General Director. 20. 09. 2006. Paule JACOMAIN, Advisor General

Vu au Consulat de Belgique
Seen at the Royal Belgian Consulate
le / on 15 AUG 2011

CONSULAAT VAN BELGIE * CONSULAT DE BELGIQUE * HO CHI MINH VILLE * HO CHI MINH STAD

Dominique CASIER
Consul de Belgique

SỞ NGOẠI VỤ
THÀNH PHỐ HỒ CHÍ MINH

HỢP PHÁP HÓA LÃNH SỰ

Số: 27835 */LS-HPH/ 2011*

Chứng thực chữ ký của Ông/Bà:

Dominique Casier

và con dấu của:

Lãnh sự quán Bỉ tại Tp. Hồ Chí Minh

Tp. Hồ Chí Minh, ngày *16/08/2011*

TL. Giám đốc

KT. Trưởng Phòng Lãnh sự

Phó Trưởng phòng

Nguyễn Duy Khiêm