



Colenta Labortechnik GmbH & Co. KG

Neunkirchnerstrasse 117
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AUSTRIA

Date: 18. 08. 2022
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Reference code: 3495301
Certificate No.: 3495301-024
Issued for: VIETNAM

Certificate of free sale

The Austrian Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen) as defined by the Austrian Medical Device Legislation hereby certifies that

- the manufacturer (or authorised representative) has its registered place of business in Austria and
 - the medical device/s and/or in vitro medical devices listed in the attachment (1 page)
- may be marketed in the EU, in the EEA and therefore in Austria and may be exported.

This Free Sales Certificate is valid until **August 18, 2024** unless a relevant certificate from a notified body loses its validity and prior to that date will not be renewed.

This Free Sales Certificate is not valid for use within the EEA and Turkey.

On behalf of the Austrian Federal Office for Safety in Health Care



Mag.^a Kerstin Konrad

7.

Attachment
Manufacturer
Colenta Labor
Neunkirch
2700 N
AUG


Die Echtheit der Unterschrift des (der)
Mag. Kerstin KONRAD
Bundesamt für Sicherheit im Gesundheitswesen
sowie des vorliegenden Amtssiegels wird bestätigt.

Wien, am **19. AUG. 2022**
Bundesministerium für europäische
und internationale Angelegenheiten

Stefan Raucher 26342/22
Stefan RAUSCHER Prot.Nr.

Verwaltungsabgabe € 3,20 entrichtet
Beglaubigungsgebühr € 14,30 entrichtet




ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI CH ẢO
EMBASSY OF THE S.R. OF VIETNAM IN THE REPUBLIC OF AUSTRIA
CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION
Việt Nam

1. Quốc gia
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (bà) **Stefan RAUSCHER** ký
has been signed by

3. với chức danh **Viên chức Bộ Ngoại giao Áo**
acting in the capacity of

4. và con dấu của: **Bộ Ngoại giao Áo**
bears the seal/stamp of

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại **Viên** 6. Ngày: **05/9/2022**
at the

7. Cơ quan cấp: **Đại sứ quán Việt Nam tại Áo**
by

8. Số: **630** / **CNLS/HPHLS/2022**
Nº

Ký tên và đóng dấu
Signature and seal/stamp

Trưởng phòng Lãnh sự
Trần Hương Ly



Manufacturer

Colenta Labortechnik GmbH & Co. KG
 Neunkirchnerstrasse 117
 2700 Wiener Neustadt
 AUSTRIA

CE marking (all products) according to Regulation (EU): 2017/745

Additional Parts, Accessories:

| REF / Article No. | Product | Firmware Version | Basic-UDI-DI | Notified Body Certificate Identification-/Certificate-No. |
|-------------------------------|--|------------------|-------------------------|---|
| DX16656411 | DICOM Printer HighCap Xp | V10.x | 912010420DICOMPrinter6B | — |
| DX16610376 | DICOM Printer HighCap XLp | V1.x | 912010420DICOMPrinter6B | — |
| DL35x43 (REF 47410 29044) | <u>Mediphot DL</u> – Dry Laser Imaging Film 35x43cm (14"x17") - 100 sheets | — | 912010420DLFilm43 | — |
| DL26x36 (REF 47410 29038) | <u>Mediphot DL</u> – Dry Laser Imaging Film 26x36cm (10"x14") - 150 sheets | — | 912010420DLFilm43 | — |
| DL25x30 (REF 47410 29040) | <u>Mediphot DL</u> – Dry Laser Imaging Film 25x30cm (10"x12") - 150 sheets | — | 912010420DLFilm43 | — |
| DL20x25 (REF 47410 29039) | <u>Mediphot DL</u> – Dry Laser Imaging Film 20x25cm (8"x10") - 150 sheets | — | 912010420DLFilm43 | — |
| DLM26x36 (REF 47410 29041) | Mediphot DLM – Dry Laser Mammography Imaging Film 26x36cm (10"x14") - 150 sheets | — | 912010420DLMFilmAH | — |
| DLM25x30 (REF 47410 29043) | Mediphot DLM – Dry Laser Mammography Imaging Film 25x30cm (10"x12") - 150 sheets | — | 912010420DLMFilmAH | — |
| DLM20x25 (REF 47410 29042) | Mediphot DLM – Dry Laser Mammography Imaging Film 20x25cm (8"x10") - 150 sheets | — | 912010420DLMFilmAH | — |