



Hospital Novamed  
Attn. Mr. I. Vlas  
Strada Tudor Strica 30  
Chisnau 2038  
Moldova

September 15th 2021, Hilvarenbeek – The Netherlands

Dear Mr. Vlas,

Please find attached the following documents:

- Extract from the Chamber of Commerce with legalization from the Consular Service Centre
- ISO 9001 certificate with legalization and apostille from the Dutch Court
- Statement of product portfolio MDT X-Ray

Do not hesitate to contact us in case you do have further questions.

Met vriendelijke groet,

With kind regards,

A handwritten signature in blue ink, appearing to read 'Janssen', is written over a horizontal line.

**Sophie Janssen**  
*Chief Executive Officer*



Hilvarenbeek – The Netherlands

Tel: +31 (0)13 5287149 | Mail: [s.janssen@mdt.nl](mailto:s.janssen@mdt.nl) | [www.mdtxray.com](http://www.mdtxray.com)





## Statement MDT X-Ray

MDT X-RAY BV, Hilvarenbeek is a manufacturer of personal protective equipment and we can confirm that we meet all the applicable essential safety requirements of the Regulation (EU) 2016/425 of 9 March 2016 concerning the harmonization of the Member States legislation relative to personal protective equipment (see EU TYPE EXAMINATION CERTIFICATE Nr 031/2020/0891).

For the argumentation the following standards are used:

*IEC 61331-3*                      *Protective devices diagnostics medical X-radiation – Part 3: Protective clothing, eyewear and protective patient shields*

*EN ISO 13688:2013*        *Protective clothing – General requirements*

We can confirm the trade names of following items produced by MDT X-RAY BV:

- **X-RAY Protection:**
  - Vest and Kilt;
    - VK-A, VK-B, VK-C, VK-CXL, VK-D, VK-E, VK-F, VK-FXL
    - FC-vest S; FC-vest M, FC-vest L, FC-vest XL
  - Coat; Coat-A, Coat-B, Coat-C, Coat-CXL, Coat-D, Coat-E, Coat-F, Coat-FXL
  - Front; Front S, Front M, Front L, Front XL
  - X-RAY Thyroid Protector; TM-3, TS-4, Vipe
  - Head Protection; HP-XS/S, HP-M, HP-XL/L, HP-XXL, TOTAL-HP
  - Lower Leg Protection; LLP
  - Detachable Shoulder Protection; DSP-1
  - Universal Gonad Protection; GP-S, GP-M, GP, L, GP-SET, GP-Belt
  - Eye protection; Focus, Discovery, Delta, Cross
- **Apron racks;** MAR-M10, MAR-M5, TRACK 5/10, MAW-5, MDT-E, AH

Issued by MDT X-RAY BV, on September 15 2021

  
**Sophie Jaussen**  
*Chief Executive Officer*





# QUALITY MANAGEMENT SYSTEM CERTIFICATE

## ISO 9001 : 2015

*BQA nv hereby declares that the management system of MDT XRAY BV and SOPHISTICATI Portugal Lda*



**X-RAY**

*located at Bukkumweg, 26 – 5081 CT Hilvarenbeek – Nederland and  
Travessa João Veiga Dos Anjos No 76 Lote 232, 4470-439 Moreira Maia, Portugal, has been examined  
and found in conformity with the ISO 9001, edition 2015, standard for the following application field:*

***Design and production of radiation protective clothing and accessories***

*This certificate has been issued by BQA nv according to its quality manual concerning the certification of  
systems, and after concluding the contract of certification N° CER\_IUY\_QMS\_17-3-2020\_580\_N  
under which the company accepts a regular control of its management system.*

**Certificate N° BQA\_QMS\_C\_2020580**

**Issue date 2020-03-17**

**Valid until 2023-03-16**



Bukkumweg 26

5081 CT Hilvarenbeek, The Netherlands

T: +31-(0)13-5287149

xray@mdt.nl www.mdt.eu

**D. SIMOENS**  
Director

**Sophisticati**  
Sophisticati Portugal, Unipessoal Lda.  
Travessa de Joao Veiga Anjos 76 LT 232  
Zona Industrial da Maia I sector IX Maia  
4470-440 Maia



## Business Register extract

### Netherlands Chamber of Commerce

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**CCI number** 18037407

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**Page** 1 (of 2)

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#### Legal entity

RSIN	801563501
Legal form	Besloten Vennootschap (comparable with Private Limited Liability Company)
Statutory name	MDT Medical Development & Technology Medical Instruments Division B.V.
Corporate seat	Oisterwijk
First entry in Business Register	03-06-1993
Date of deed of incorporation	27-05-1993
Issued capital	EUR 18.151,21
Paid-up capital	EUR 18.151,21
Filing of the annual accounts	The annual accounts for the financial year 2019 were filed on 29-07-2020.

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#### Company

Trade name	MDT X-RAY
Company start date	01-01-1985
Activities	SBI-code: 32502 - Manufacture of medical instruments and supplies (no dental laboratories) SBI-code: 46462 - Wholesale of medical and dental instruments, nursing and orthopaedic articles and laboratory equipment
Employees	0

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#### Establishment

Establishment number	000017082048
Trade name	MDT X-RAY
Visiting address	Bukkumweg 26, 5081CT Hilvarenbeek
Telephone number	+31135287149
Date of incorporation	01-01-1985
This legal person has conducted the establishment since	27-05-1993
Activities	SBI-code: 32502 - Manufacture of medical instruments and supplies (no dental laboratories) SBI-code: 46462 - Wholesale of medical and dental instruments, nursing and orthopaedic articles and laboratory equipment For further information on activities, see Dutch extract.
Employees	0

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#### Sole shareholder



Gezien voor legalisatie van de handtekening  
The undersigned legalises the signature

## Business Register extract Netherlands Chamber of Commerce

van/of **C.M.H.L. Lourens**

De minister van Buitenlandse Zaken, voor deze,  
For the minister of Foreign Affairs,

CCI number 18037407



NLD522977

Page 2 (of 2)

26 apr 2021 - S.H. Baidjoe

Name	MDT Medical Development & Technology B.V.
Visiting address	Bukkumweg 26, 5081CT Hilvarenbeek
Registered under CCI number	18027829
Sole shareholder since	18-01-2001

### Board members

Name	MDT Medical Development & Technology B.V.
Visiting address	Bukkumweg 26, 5081CT Hilvarenbeek
Registered under CCI number	18027829
Date of entry into office	18-01-2001
Title	Director authorised to represent the company
Powers	Solely/independently authorised

Name	Janssen, Sophie Erna Maria Frédérique
Date of birth	12-06-1988
Date of entry into office	01-10-2020 (registration date: 20-04-2021)
Title	Director authorised to represent the company
Powers	Solely/independently authorised

Extract was made on 20-04-2021 at 16.37 hours.

For extract



C.M.H.L. Lourens, Manager Centrale Productie en Backoffice