

	Processus Management	Création	16.03.2010
		Version	2
		Mise à jour	25.05.2021

DECLARATION OF CONFORMITY

The certification body of Bureau Veritas AG, Grosssächerstrasse 25 - CH-8104 Weiningen – Switzerland, confirm that,

Manufactures D’Outils Dumont SA

Rue Théodore Dumont I
2924 Montignez / Switzerland

have established and are maintaining a quality management system according to

ISO 9001:2015

(Certificate Registration No.: CH10846021)

EN ISO 13485:2016

(Certificate No.: CH10846021)

for the following area

Design, Development, manufacturing of non-sterile reusable surgical tweezers and forceps (of class I)

Furthermore we have implemented the conformity assessment procedure as per annex II, clause 3 of the Medical Device Directive 93/42/EEC of dune 14", 1993 for medical products


By labeling the products

Dumont Tweezers
as per attached list

with the CE mark

Manufactures D’Outils Dumont SA confirm,
That the company follows the essential requirements according to MDD 93/42/JEEC Annex I.

Manufactures D’Outils Dumont SA, 25.05.2021


 David A. Sgobero
 Regulatory Affairs


 Stephane Mure
 Regulatory Affairs

Attachment to Declaration for Dumont Tweezers for Carl Roth

Dumont-Ref #	Art.-Nr.	Art.-Name	DoC
I0008-DIRPY1-SM	HTX1.I	Präzisionspinzette, 1 mm Spitze, Spezialform 1 St	MDD
I0008-DIRPY2-SM	HTX2.I	Präzisionspinzette, 2 mm Spitze, Spezialform 1 St	MDD
TIP-IRPY1-DEL	HTX3.I	Ersatz-Kunststoffspitzen 1 mm f. P.pinzette 2 St	MDD
TIP-IRPY2-DEL	HTX4.I	Ersatz-Kunststoffspitzen 2 mm f. P.pinzette 2 St	MDD
0102-1-PO	K337.I	Dumont Pinzette Nr. 1	MDD
0102-2-PO	K338.I	Dumont Pinzette Nr. 2	MDD
0102-3-PO	K339.I	Dumont Pinzette Nr. 3	MDD
0102-3C-PO	K340.I	Dumont Pinzette Nr. 3c	MDD
0102-4-PO	K341.I	Dumont Pinzette Nr. 4	MDD
0108-5-PO	K342.I	Dumont Pinzette Nr. 5	MDD
0108-5/45-PO	K343.I	Dumont Pinzette Nr.5/45°	MDD
0102-7-PO	K344.I	Dumont Pinzette Nr. 7	MDD
0208-5SPSF-PS	LH52.I	Dumont Präzisionspinzette Nr. 5SPSF, 1 St	MDD
0208-5-PO	LH53.I	Dumont Präzisionspinzette Nr. 5, 1 St	MDD
0208-5/45-PO	LH54.I	Dumont Präzisionspinzette Nr. 5/45° 1 St	MDD
0508-L7-PO	LH58.I	Dumont Präzisionspinzette Nr. L7, 1 St	MDD
0508-SS/45-PO	LH60.I	Dumont Präzisionspinzette Nr. SS/45°, 1 St	MDD
0304-5-CO	LH63.I	Dumont Präzisionspinzette Nr. 5, 1 St	MDD
0304-7-CO	LH65.I	Dumont Präzisionspinzette Nr. 7, 1 St	MDD
0203-5-PO	LH66.I	Dumont Präzisionspinzette Nr. 5, 1 St	MDD
0203-5/45-PO	LH67.I	Dumont Präzisionspinzette Nr. 5/45°, 1 St	MDD
0203-5/45-PO	LH68.I	Dumont Präzisionspinzette Nr. 4, 1 St	MDD
0203-3-PO	LH71.I	Dumont Präzisionspinzette Nr. 3, 1 St	MDD
0103-2EI/2-PO	LH74.I	Dumont Präzisionspinzette Nr. 2EI/2, 1 St	MDD
0209-5-PO	LH75.I	Dumont Präzisionspinzette Nr. 5, 1 St	MDD
0103-5-PO	LH79.I	Dumont Präzisionspinzette Nr. 5, 1 St	MDD
0103-7-PO	LH81.I	Dumont Präzisionspinzette Nr. 7, 1 St	MDD
0302-5-PO	PK78.I	Dumont® Präzisionspinzette Typ 5, eco 1 St	MDD
0207-5TI-PO	TE59.I	Präzisionspinzette, Typ 5, Titan 1 St.	MDD
0107-3TI-PO	TE60.I	Präzisionspinzette, Typ 3, Titan 1 St.	MDD
0107-7TI-PO	TE61.I	Präzisionspinzette, Typ 7, Titan 1 St.	MDD
0302-3-PO	TE62.I	Präzisionspinzette, Typ 3, Inox02 1 St.	MDD
0302-7-PO	TE63.I	Präzisionspinzette, Typ 7, Inox02 1 St.	MDD
0203-N5-PO	TE64.I	Präzisionspinzette, Typ N5, Dumoxel 1 St.	MDD
0203-N7-PO	TE65.I	Präzisionspinzette, Typ N7, Dumoxel 1 St.	MDD
0302-AA-PO	TE66.I	Präzisionspinzette, Typ AA, Inox02 1 St.	MDD
0302-AA-CO	TE67.I	Präzisionspinzette, Typ AA, Inox02 Epoxid 1 St.	MDD
0102-SSI35-PO	TE68.I	Präzisionspinzette, Typ SSI35, Inox02 1 St.	MDD
0208-SSI35-PO	TE69.I	Präzisionspinzette, Typ SSI35, Inox08 1 St.	MDD
0208-55-PO	TE70.I	Präzisionspinzette, Typ 55, Inox08 1 St.	MDD
0209-55-PO	TE71.I	Präzisionspinzette, Typ 55, Dumostar 1 St.	MDD
0203-M5SA-PO	TE72.I	Präzisionspinzette, Typ M5, Dumoxel 1 St.	MDD
0108-5/15-PO	TE73.I	Präzisionspinzette, Typ 5/15, Inox08 1 St.	MDD
0103-6-PO	TE75.I	Präzisionspinzette, Typ 6, Dumoxel 1 St.	MDD
0508-7XL-PO	TE76.I	Präzisionspinzette, Typ 7XL, Inox08 1 St.	MDD
0102-7B-PO	TE77.I	Präzisionspinzette, Typ 7B, Inox02 1 St.	MDD
0301-15AE SD-CO	TE78.I	Präzisionspinzette, Typ 15AE SD-CO, Karbon 1 St.	MDD

BUREAU VERITAS
Certification



Certificate
for

Manufactures D'Outils Dumont SA
Rue Théodore Dumont 1, 2924 Montignez / Switzerland

Bureau Veritas Certification hereby confirms that the management system of the above-mentioned organisation has been assessed and complies with the requirements set out in the following standards/regulations.

Standards/Regulations:

SN EN ISO 9001:2015

The management system comprises:

**Design, development, manufacturing, trading and repair
of tweezers and forceps**

Date of initial certification:	08.11.2016	End of the last certification cycle:	07.11.2019
Date of recertification:	01.11.2019	Start of the new certification cycle:	22.11.2019

The requirements of the standards/regulations must be continuously fulfilled throughout the validity of this certificate. This will be ensured and guaranteed through regular monitoring by Bureau Veritas Certification.
This certificate is valid until: **07.11.2022**

Bureau Veritas Certification will provide information on the validity of this certificate on request at any time. Additional information on the management system and the area of applicability should be obtained from the organisation itself.

Certificate number: **CH10846021** Version: **1** Issue date: **22.11.2019**

Pascal Singh

Bureau Veritas Switzerland AG,
Grossächerstrasse 25, CH-8104 Weiningen ZH



BUREAU VERITAS
Certification



Certificate
for

Manufactures D'Outils Dumont SA
Rue Théodore Dumont 1, 2924 Montignez / Switzerland

Bureau Veritas Certification hereby confirms that the management system of the above-mentioned organisation has been assessed and complies with the requirements set out in the following standards/regulations.

Standards/Regulations:

SN EN ISO 13485:2016

The management system comprises:

**Design, development, manufacturing of non-sterile reusable surgical
tweezers and forceps**

Date of initial certification:	22.11.2019	End of the last certification cycle:	--
Date of recertification:	--	Start of the new certification cycle:	22.11.2019

The requirements of the standards /regulations must be continuously fulfilled throughout the validity of this certificate. This will be ensured and guaranteed through regular monitoring by Bureau Veritas Certification.

This certificate is valid until: **21.11.2022**

Bureau Veritas Certification will provide information on the validity of this certificate on request at any time. Additional information on the management system and the area of applicability should be obtained from the organisation itself.

Certificate number: **CH10846021** Version: **1** Issue date: **22.11.2019**

Pascal Singh

Bureau Veritas Switzerland AG,
Grosssäckerstrasse 25, CH-8104 Weiningen ZH

