CERTIFICATO CE
EC CERTIFICATE

n. **ECM19MDD001 rev. 2**

Data di prima emissione *Date of first issue*	*30/01/2019*
Data di emissione *Date of issue*	*30/01/2019*
Data di ultimo rinnovo *Date of last renewal*	
Data di revisione *Date of revision*	*26/03/2021*
Data di scadenza *Expiry date*	*29/01/2024*

CERTIFICATO CE
EC Certificate

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)
Issued according to 93/42/EEC directive – Annex II (excl. clause 4)

Richiedente
Applicant

Ragione Sociale *Company Name*	**Veldana Medical SA**
Sede Legale *Legal address*	**Av. Riond-Bosson 14, 1110 Morges**
Località *Place*	**Switzerland**
Sito produttivo *Place of production*	**Idem**
Dispositivo Medico *Medical device*	**Single use disposable sheath for laparoscopic surgery** **Thermal endometrial ablation devices** **Thermal Balloon Endometrial Ablation Catheter**
Identificato come *Identified as*	**Vedi allegato al presente certificato** **See the annex of this certificate**

ECM, Organismo Notificato n° 1282 ha verificato il Sistema Qualità in accordo all'allegato II (escluso il p.to 4) della direttiva 93/42/CEE) e ha rilevato che ne soddisfa i requisiti.
Si fa riferimento al rapporto di audit di emissione del presente certificato del 21 febbraio 2019; rif. piano di certificazione: VELDANA MEDICAL SA -18.09

ECM, Notified Body n° 1282 has verified the Quality System in accordance with annex II (excluding clause 4) of the 93/42/EEC directive and found that it meets aforesaid requirements.
Reference to the audit report related to issue of the present certificate dated 21th February 2019; ref. certification plan: VELDANA MEDICAL SA -18.09

Firma autorizzata
Authorized signature

(Federica Secchi - Technical Director)

Ente Certificazione Macchine srl
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CERTIFICATO CE
EC CERTIFICATE

n. **ECM19MDD001 rev. 2**

Data di prima emissione *Date of first issue*	*30/01/2019*
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Allegato al Certificato CE
Annex to EC Certificate

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)
Issued according to 93/42/EEC directive – Annex II (excl. clause 4)

Elenco dei Dispositivi Medici inclusi in questo certificato
List of Medical Devices included in this certificate

Descrizione ***Description***	**Classe di rischio** ***Risk class***	**Codice NBOG** ***NBOG code***	**Modello** ***Model***	**Taglie** ***Sizes***
Single use disposable sheath for laparoscopic surgery	IIa	MD 0106 + MDS 7006	ACUBLO	ACU-CUST-014 ACU-CUST-015 ACU-CUST-016 ACU-CUST-017
Medical electrical device for thermal endometrial ablation	IIb	MD 1104 + MDS 7010	Cavaterm™ 3.1 Central Unit	NA
Thermal Balloon Endometrial Ablation Catheter compatible with Cavaterm™ Central Unit	IIb	MD 1104 + MDS 7006	Cavaterm™ Plus Catheter	NA

Firma autorizzata
Authorized signature

(Federica Secchi - Technical Director)

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Data: 02 Ottobre 2024
Date: October the 02nd, 2024

A CHI DI COMPETENZA
TO WHOMSOEVER IT MAY CONCERN

Il presente documento modifica la lista dei Dispositivi Medici inclusi in questo Certificato CE n.**ECM19MDD001 rev. 2** del 26 Marzo 2021 a **Veldana Medical SA.**
This document amends the list of Medical Devices included in this EC Certificate n. ***ECM19MDD001 rev. 2*** *issued on March the 26th, 2021 to* **Veldana Medical SA.**

Ente Certificazione Macchine s.r.l (Organismo Notificato n. 1282), conferma che la lista dei Dispositivi Medici inclusi in questo Certificato CE n. **ECM19MDD001 rev. 2** del 26 Marzo 2021 è la seguente:
Ente Certificazione Macchine s.r.l *(Notified Body No. NB 1282), confirms that the list of Medical Devices included in this EC Certificate n.* ***ECM19MDD001 rev. 2*** *issued on March the 26th, 2021 is the following:*

Elenco dei Dispositivi Medici inclusi in questo certificato
List of Medical Devices included in this certificate

Descrizione *Description*	**Classe di rischio** *Risk class*	**Codice NBOG** *NBOG code*	**Modello** *Model*	**Taglie** *Sizes*
Single use disposable sheath for laparoscopic surgery	IIa	MD 0106 + MDS 7006	ACUBLO	ACU-CUST-015-B ACU-CUST-017-B

Il presente documento deve essere sempre presentato unitamente al certificato CE.
This document must be always submitted together with the EC certificate.

Luca Bedonni
Ente Certificazione Macchine s.r.l

Ente Certificazione Macchine

Notified Body n. 1282 - Testing Laboratory – Nr. 121697 PJLA
Authorized Training Body n. 6737 - Inspection Body

CONFIRMATION LETTER IN THE FRAMEWORK OF REGULATION EU 2023/607

FOR "LEGACY" DEVICES ACCORDING TO DIRECTIVE 93/42/EEC

REFERENCE N° 07/F

ENTE CERTIFICAZIONE MACCHINE SRL
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ENTE CERTIFICAZIONE MACCHINE

Veldana Medical SA

Single Registration Number: CH-MF-000015832
Address: Avenue Riond-Bosson 14, 1110 Morges, Switzerland
Referent: Mr. Gianluca Lettieri

CONFIRMATION LETTER IN THE FRAMEWORK OF REGULATION EU 2023/607

FOR "LEGACY" DEVICES
ACCORDING TO DIRECTIVE 93/42/EEC

Confirmation of the status of a formal application, written agreement, and appropriate surveillance activity in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Ente Certificazione Macchine srl (ECM), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **1282 on NANDO**, confirms to have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and to have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with **Veldana Medical SA**.

In addition, this letter confirms that **ECM**, where relevant, has signed a written agreement with **Veldana Medical SA** governing transfer of the surveillance activitiy in accordance with Article 120, paragraph 3e of MDR as amended by Regulation (EU) 2023/607.

The devices covered by the formal application and the written agreements mentioned above are identified in the Tables below. **Table 1** identifies devices for which an MDR application has been received, written agreement concluded, and for which **ECM** is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. **Table 2** identifies devices for which an MDR application has been received and a written agreement concluded, but **ECM** has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR repectively, by 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

ENTE CERTIFICAZIONE MACCHINE SRL
LUCA BEDONNI

Table 1 Devices covered by this letter and for which ECM is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application
ACUBLO	☐ Class IIb device ☒ Class IIa device ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☐ MDD/AIMDD device identification: Device name ☒ Not applicable	☐ MDD/AIMDD Certificate ECM19MDD001 issued by Ente Certificazione Macchine s.r.l., NB Number 1282 ☐ Not applicable

Table 2 Devices covered by this letter and for which ECM is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application
Device #1	☐ Class IIb device ☐ Class IIa device ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☐ MDD/AIMDD device identification: Device name ☐ Not applicable	☐ MDD/AIMDD Certificate Certificate number issued by NB name and NANDO number aggiungere campi (nel caso di dispositivi su più certificati), e cancellare la presente frase. ☐ Not applicable