

## DICHIARAZIONE DI CONFORMITÀ CE PER DISPOSITIVI MEDICI

### EC Declaration of Conformity for medical devices

La sottoscritta  
*We, the undersigned*                      **CID S.p.A. – Strada per Crescentino 13040 Saluggia (VC) - Italy**

dichiara sotto la propria responsabilità che i prodotti sotto elencati  
*hereby declare under our sole responsibility that the products listed here below*

Prodotto - <i>Product</i>	codice prodotto - <i>product code</i>	codice modello <i>model code</i>	Classe <i>Class</i>	Certificato CE di Prodotto <i>EC Product Certificate</i>	data ril. <i>issue date</i>
CRE8™ EVO	ICLX2009	LX2009	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2013	LX2013	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2016	LX2016	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2020	LX2020	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2026	LX2026	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2033	LX2033	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX22509	LX22509	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX22513	LX22513	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX22516	LX22516	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX22520	LX22520	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX22526	LX22526	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX22533	LX22533	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX22540	LX22540	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2509	LX2509	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2513	LX2513	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2516	LX2516	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2520	LX2520	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2526	LX2526	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2533	LX2533	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2540	LX2540	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX2546	LX2546	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX27509	LX27509	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX27513	LX27513	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX27516	LX27516	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX27520	LX27520	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX27526	LX27526	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX27533	LX27533	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX27540	LX27540	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX27546	LX27546	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX3009	LX3009	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX3013	LX3013	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX3016	LX3016	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX3020	LX3020	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX3026	LX3026	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX3033	LX3033	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX3040	LX3040	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX3046	LX3046	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021
CRE8™ EVO	ICLX3509	LX3509	III	EPG-0335-21 <i>Add.II-II</i>	4th May 2021

CRE8™ EVO	ICLX3513	LX3513	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX3516	LX3516	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX3520	LX3520	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX3526	LX3526	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX3533	LX3533	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX3540	LX3540	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX3546	LX3546	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX4009	LX4009	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX4013	LX4013	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX4016	LX4016	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX4020	LX4020	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX4026	LX4026	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX4033	LX4033	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX4513	LX4513	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX4516	LX4516	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX4520	LX4520	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX4526	LX4526	III	EPG-0335-21 Add.II-II	4th May 2021
CRE8™ EVO	ICLX4533	LX4533	III	EPG-0335-21 Add.II-II	4th May 2021

emessi dall'Istituto Superiore di Sanità, Viale Regina Elena 299 - 00161 Roma, Organismo Notificato n° 0373, sono conformi secondo l'allegato 2 della Direttiva Europea 93/42/CEE e successivi emendamenti, concernente i dispositivi medici, attuato con Dlgs. 46 del 24.02.1997.

*issued by the Istituto Superiore di Sanità, as Notified Body n° 0373, are conforming according to Annex 2 of Directive 93/42/EEC and subsequent updating concerning medical devices, transposed by Dlgs. 46 of 24.02.1997.*

Si garantisce inoltre che i prodotti sopra indicati sono in accordo con tutti i requisiti applicabili della citata Direttiva.  
*It is also guaranteed that the indicated products meet all applicable provisions of the named Directive.*

Questa dichiarazione è emessa sulla base del Certificato di Approvazione del Sistema di Garanzia della Qualità n°  
*This declaration is issued based on the Quality Assurance System Approval Certificate n°*

**QCT-0169-21 Add. 02-21 Data di scadenza/expiry date 26<sup>th</sup> May 2024**

La presente DICHIARAZIONE DI CONFORMITÀ CE è valida per i dispositivi prodotti sotto la responsabilità della CID S.p.A.  
*This EC DECLARATION OF CONFORMITY is valid for the medical devices manufactured under CID S.p.A. responsibility.*

Il Dispositivo medico Cre8™ EVO verrà prodotto sia dal fabbricante CID S.p.A. sito in Strada per Crescentino snc 13040-Saluggia (VC) Italia, sia dal terzista ALVIMEDICA TIBBI ÜRÜNLER SAN. VE DIS TICARET A.S., Istanbul Trakya Serbest Bölgesi, Ferhatpasa SB Mahallesi Atatürk Bulvarı No. 16, 34540, Çatalca, Istanbul, Turkey.

The medical device Cre8™ EVO will be produced both by the Manufacturer CID S.p.A. located in Strada per Crescentino snc 13040-Saluggia (VC) Italia, and ALVIMEDICA TIBBI ÜRÜNLER SAN. VE DIS TICARET A.S., Istanbul Trakya Serbest Bölgesi, Ferhatpasa SB Mahallesi Atatürk Bulvarı No. 16, 34540, Çatalca, Istanbul, Turkey.

La presente dichiarazione scade in data: **26 Maggio 2024**  
*This declaration expires on: 26<sup>th</sup> May 2024*

Saluggia, li 5 Maggio 2021  
5<sup>th</sup> May 2021



Vittoria Allono -CID S.p.A.  
RAPPRESENTANTE DELLA DIREZIONE MANAGEMENT REPRESENTATIVE



Ahmet Ozcan - CID S.p.A.  
DIREZIONE AZIENDALE GENERAL MANAGEMENT