

Number: 2262886TD01

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Manufacturer:

Assut Medical Sarl

Avenue de Rochettaz 57

1009 Pully

Switzerland

SRN ID.: CH-MF-000009358

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

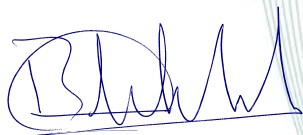
0344

Supplement to certificate: 2194636CN

Authorized Representative: MT Promedt Consulting GmbH
Ernst-Heckel-Strasse 7
66386 St. Ingbert
Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745. For placing these products on the market an Annex IX EU Quality Management System certificate is also required.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Principal Certification Manager

First Issued: **24 January 2025**

Date: **1 September 2025**

Expiry date: **1 January 2030**

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s):

Class III				
Basic UDI-DI: 07613406ACLPGA8T				Intended Purpose: AssuCryl® braided is intended for use in general soft tissue approximation and / or ligation, including use in ophthalmic surgery but not in cardiovascular surgery, microsurgery and neural tissue
Device Name: AssuCryl®				
Type:				
H0101010201 POLYGLYCOLIC ACID MULTIFILAMENT				
Models:				
Colour	Length (cm)	USP sizes	EP sizes (Metric)	
Violet	10 - 400	8-0; 7-0; 6-0; 5-0; 4-0; 3-0; 2-0; 0; 1; 2; 3&4	0.4; 0.5; 0.7; 1; 1.5; 2; 2.5; 3; 3.5; 4; 5; 6	
Undyed		6-0; 5-0; 4-0; 3-0; 2-0; 0; 1; 2	0.7; 1; 1.5; 2; 2.5; 3; 3.5; 4; 5	
With and without needles				
Basic UDI-DI: 07613406ACLRPGACE				Intended Purpose: AssuCryl® Rapid is intended for use in general soft tissue approximation and / or ligation where only short-term wound support is required and when rapid absorption is indicated. It is also indicated for superficial skin closure, plastic surgery, episiotomy wound healing, oral mucosa and conjunctival ophthalmic surgery.
Device Name: AssuCryl® Rapid				
Type:				
H0101010201 POLYGLYCOLIC ACID MULTIFILAMENT				
Models:				
Colour	Length (cm)	USP sizes	EP sizes (Metric)	
Undyed	10 - 400	6-0; 5-0; 4-0; 3-0; 2-0; 0; 1; 2	0.7; 1; 1.5; 2; 2.5; 3; 3.5; 4; 5	
With and without needles				
Basic UDI-DI: 07613406ACLLPGLAHT				Intended Purpose: AssuCryl® Lactin sutures are intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery but not in cardiovascular surgery, microsurgery and neural tissue.
Device Name: AssuCryl® Lactin				
Type:				
H0101010202 POLYGLYCOLIC WITH LACTIC ACID MULTIFILAMENT				
Models:				
Colour	Length (cm)	USP sizes	EP sizes (Metric)	
Violet	10 - 400	8-0; 7-0; 6-0; 5-0; 4-0; 3-0; 2-0; 0; 1; 2; 3&4	0.4; 0.5; 0.7; 1; 1.5; 2; 2.5; 3; 3.5; 4; 5; 6	
Undyed		6-0; 5-0; 4-0; 3-0; 2-0; 0; 1; 2	0.7; 1; 1.5; 2; 2.5; 3; 3.5; 4; 5	
With and without needles				

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Class III				
Basic UDI-DI: 07613406ACLMSPDOLC				
Device Name: AssuCryl® MonoSlow Type: H0101010101 POLYDIOXANONE MONOFILAMENT				
Intended Purpose: AssuCryl® MonoSlow monofilament sutures are intended for use in general soft tissue approximation and/or ligation. AssuCryl® MonoSlow should not be used in cases where an extended wound support over a period of 6 weeks is desirable.				
Models:				
Colour	Length (cm)	USP sizes	EP sizes (Metric)	
Violet	10 - 400	7-0; 6-0; 5-0; 4-0; 3-0; 2-0; 0; 1; 2	0.5; 0.7; 1; 1.5; 2; 2.5; 3; 3.5; 4; 5	
With and without needles				
Basic UDI-DI: 07613406ACLMRPGCL25				
Device Name: AssuCryl® MonoRapid Type: H0101010103 POLIGLECAPRONE AND DERIVATIVES MONOFILAMENT				
Intended Purpose: AssuCryl® MonoRapid is intended for use in soft tissue closing and/or ligation when only short term support of the wound is required and rapid absorption is indicated. It is also ideal for sutures of the epidermis, plastic surgery, healing an episiotomy, suture of the mucous membranes				
Models:				
Colour	Length (cm)	USP sizes	EP sizes (Metric)	
Violet	10 - 400	6-0; 5-0; 4-0; 3-0; 2-0; 0; 1; 2	0.7; 1; 1.5; 2; 2.5; 3; 3.5; 4; 5	
Undyed		6-0; 5-0; 4-0; 3-0; 2-0; 0; 1; 2	0.7; 1; 1.5; 2; 2.5; 3; 3.5; 4; 5	
With and without needles				

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	24-01-2025	2194636CN12	first issue
1	01-08-2025	2194636CN13	revised
2	01-09-2025	2194636CN14	revised

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