

EU DECLARATION OF CONFORMITY EU KONFORMITÄTSERKLÄRUNG

90.1684.05



The manufacturer

Der Hersteller

CODAN Medizinische Geräte GmbH
Stig Husted-Andersen Straße 11
23738 Lensahn, Germany

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codan@codan.de

Single Registration Number: DE-MF-000005286

declares sole responsibility, that the sterile medical devices specified below

bestätigt in seiner alleinigen Verantwortung, dass die nachstehend aufgeführten sterilen Medizinprodukte

CODAN Medical Device File/ Description /
CODAN Medizinproduktakte/ Beschreibung:

01/ Infusion

Basic UDI-DI / Basis UDI-DI:

405569801020000ER

Risk Class/ Classification Rule /
Risikoklasse/ Klassifizierungsregel:

Ila/ 2

are developed, manufactured, controlled, and placed on the market in accordance with the provisions of the Regulation (EU) 2017/745 on medical devices, appropriate standards, and common specifications, where applicable.

gemäß den Bestimmungen der Verordnung (EU) 2017/745 über Medizinprodukte, den anwendbaren Normen und, wo anwendbar, den gemeinsamen Spezifikationen entwickelt, hergestellt, kontrolliert und in Verkehr gebracht werden.

Applied Common Specifications /
Anwendbare gemeinsame Spezifikationen:

N/A

Conformity Assessment is carried out in accordance with Annex IX (excluding chapter II) of the Regulation (EU) 2017/745. Compliance with the procedures as defined in the Regulation (EU) 2017/745 on medical devices is supervised by the notified body

Die Konformitätsbewertung wird gemäß Anhang IX (ohne Kapitel II) der Verordnung (EU) 2017/745 durchgeführt. Die Einhaltung der in der Verordnung (EU) 2017/745 über Medizinprodukte festgelegten Verfahren wird von der Benannten Stelle überwacht

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München, Germany

Identification No. / Identifikationsnummer: **0123**

Number of Certificate / Zertifikatsnummer: **G10 010393 0534 Rev. 04**

This Declaration of Conformity is valid from /
Diese Konformitätserklärung ist gültig ab: **2024-04-17**

Valid until /
Gültig bis: **2027-02-16**

In case of essential product changes this declaration of conformity may require revision.
CODAN Medizinische Geräte GmbH is sole responsible for the content and the release of this declaration of conformity.

Bei wesentlichen Produktänderungen kann eine Revisierung dieser Konformitätserklärung erforderlich werden. Die CODAN Medizinische Geräte GmbH ist alleinverantwortlich für den Inhalt und die Freigabe dieser Konformitätserklärung.

Lensahn, 2024-04-17

Signature: 

Andreas Wenig, Plant Manager
On behalf of General Management
CODAN Medizinische Geräte GmbH



Basic UDI-DI / Basis UDI-DI:405569801020000ER

CODAN REF	Product Name / Produktname
44.2100	E25 MF-3
44.2101	E25 MF-5
44.2118	E25 MF-5 SWAN-LOCK®
44.2121	E25 MF-3 SWAN-LOCK®
44.2126	E25 MF-5
44.4821	green line® E30 MF-3 SWAN-LOCK®
44.4822	green line® E30 MF-5 SWAN-LOCK®
44.4825	green line® E30 MF-3
44.4826	green line® E30 MF-5
71.4012	E30-R
71.4020	E09
71.4021	E30
71.4024	E09
71.4027	E09
71.4100	LIGHT-SAFE E09
71.4101	LIGHT-SAFE E09
71.4103	LIGHT-SAFE E09
71.4104	LIGHT-SAFE E09 SWAN-LOCK®
71.4260	E30-R
71.4266	E30
71.4270	E30-R
71.4271	E30 SWAN-LOCK®
71.4297	E25
71.4298	E25
71.4306	E30
71.4318	E09
71.4326	E09
71.4327	E30
71.4329	E30
71.4330	E30
71.4334	E09
71.4349	E09
71.4352	E09
71.4356	E09

CODAN REF	Product Name / Produktname
71.4365	E09
71.4380	E40
71.4384	E30
71.4391	E09
71.4402	E30
71.4406	E25
71.4408	E30
71.4416	E30
71.4424	E09
71.4425	E09-R
71.4426	E09-R
71.4428	E30
71.4442	E09
71.4445	E09
71.4452	E09
71.4454	E09
71.4459	E25-R
71.4463	E09
71.4469	E30
71.4473	E09
71.4478	E30
71.4479	E30
71.4485	E09
71.4487	E30
71.4492	E30
71.4504	E30
71.4506	STERITEX® E25
71.4507	STERITEX® E25
71.4508	STERITEX® E25
71.4509	STERITEX® E25
71.4511	STERITEX® E25
71.4518	E09 SWAN-LOCK®
71.4519	STERITEX® E25 SWAN-LOCK®
71.4524	E30



CODAN REF	Product Name / Produktname
71.4525	E30
71.4526	STERITEX® E25
71.4527	STERITEX® E25
71.4528	STERITEX® E25
71.4529	STERITEX® E25
71.4531	STERITEX® E25
71.4535	E09
71.4537	STERITEX® E25
71.4538	E09 SWAN-LOCK®
71.4542	E09 SWAN-LOCK®
71.4548	STERITEX® E25
71.4550	STERITEX® E25
71.4553	E09
71.4556	STERITEX® E25
71.4558	STERITEX® E25
71.4559	E30 SWAN-LOCK®
71.4560	E30 SWAN-LOCK®
71.4565	E09 SWAN-LOCK®
71.4567	E09-R
71.4569	E09 SWAN-LOCK®
71.4576	E09
71.4577	E09-R
71.4579	E30
71.4582	E25 SWAN-LOCK®
71.4583	E30 MF-2 SWAN-LOCK®
71.4585	E09 SWAN-LOCK®
71.4586	STERITEX® E25
71.4587	STERITEX® E25
71.4589	STERITEX® E25
71.4594	E09
71.4596	E09-R
71.4597	E30 SWAN-LOCK® MF-2 SWAN-LOCK®
71.4598	E30 SWAN-LOCK® MF-5 SWAN-LOCK®
71.4804	green line® E30-R
71.4806	green line® STERITEX® E25 SWAN-LOCK®

CODAN REF	Product Name / Produktname
71.4808	green line® E09
71.4809	green line® E09
71.4811	green line® E09
71.4812	green line® E09
71.4813	green line® E09
71.4815	green line® E09
71.4820	green line® E30
71.4821	green line® E30
71.4822	green line® E30
71.4823	green line® E09 SWAN-LOCK®
71.4824	green line® STERITEX® E25 SWAN-LOCK®
71.4827	green line® E25 SWAN-LOCK®
71.4828	green line® STERITEX® E09 SWAN-LOCK®
71.4831	green line® E09 SWAN-LOCK®
71.4833	green line® STERITEX® E25
71.4836	green line® STERITEX® E09
71.4837	green line® STERITEX® E09
71.4839	green line® STERITEX® E25 SWAN-LOCK®
71.4840	green line® E25 SWAN-LOCK®
71.4841	green line® STERITEX® E25 SWAN-LOCK®
71.4842	green line® E09-R
71.4843	green line® E09-R
71.4849	green line® STERITEX® E25
71.4850	green line® STERITEX® E25 SWAN-LOCK®
71.4853	green line® STERITEX® E25 SWAN-LOCK®
71.4854	green line® STERITEX® E25 SWAN-LOCK®
71.4856	green line® E09-R
71.4861	green line® STERITEX® E25
71.4863	green line® E30
71.4868	green line® STERITEX® E09
71.5481	E30
72.3100	C09/2-R SWAN-LOCK®
72.3101	C30/3 SWAN-LOCK®
72.3133	C30/2 SWAN-LOCK®



CODAN REF	Product Name / Produktname
72.3136	C25/3-R
72.3150	C30/3
72.3152	E09/2
72.3155	C30/2-R
72.3157	E09/2-R
72.3161	C09/2-R
72.3162	C09/2 SWAN-LOCK®
72.3163	C09/2-R SWAN-LOCK®
72.3164	C09/3 SWAN-LOCK®
72.3166	C09/2-R SWAN-LOCK®
72.3168	C25/2-R SWAN-LOCK®
72.3169	C25/3-R SWAN-LOCK®
72.3172	C09/3-R
72.3173	E09/2-R
72.3177	C09/3-R SWAN-LOCK®
72.3180	C09/2-R SWAN-LOCK®
72.3183	E09/2-R
72.3186	C09/3-R
72.3187	E09/2-R
72.3191	E09/3-R
72.3192	E09/2-R
72.3194	E09/2-R SWAN-LOCK®
72.3195	E09/3-R SWAN-LOCK®
72.3198	E09/3-R SWAN-LOCK®
72.3199	C30/2
72.3200	C25/2-R
72.3203	E09/2-R
72.3220	C30/4
72.3253	C09/4-R SWAN-LOCK®
72.3256	C09/4-R
72.3260	C09/4-R SWAN-LOCK®
72.3261	C09/3-R
72.4522	E09/2-R
72.4802	green line® E09/2-R

CODAN REF	Product Name / Produktname
72.4803	green line® E09/2-R
72.4805	green line® C25/2 SWAN-LOCK®
72.4806	green line® C09/2 SWAN-LOCK®
72.4807	green line® C09/3 SWAN-LOCK®
72.4809	green line® C09/2 SWAN-LOCK®
72.4814	green line® C09/2-R SWAN-LOCK®
76.3380	STERITEX® E25
76.3460	C09/4-R SWAN-LOCK®
76.4031	E09/2-R
76.4042	TIVA Extension/2
76.4059	TIVA Extension/2
76.4064	E09/2-R
76.4836	green line® TIVA Extension/3
76.4843	green line® TIVA Extension/2
76.4864	green line® TIVA Extension/2