

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:

405569801010000EE

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: **2024-04-19**

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, 2024-04-19

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



Basic UDI-DI / Basis UDI-DI: 405569801010000EE

CODAN REF	Product Name / Produktname
25.1002	Mix-Ad Set/1
25.1059	Mix-Ad Set/1
25.1065	Mix-Ad Set/1
25.1068	Mix-Ad Set/1
25.1075	Mix-Ad Set/1
25.1081	Mix-Ad Set/1
25.1100	Mix-Ad Set/2
25.3900	CODAN Guard® Mix-Ad Set/1
25.3901	CODAN Guard® Mix-Ad Set/2
25.3902	CODAN Guard® Mix-Ad Set/3
25.4800	green line® Mix-Ad Set/1
25.4802	green line® Mix-Ad Set/1
25.4804	green line® Mix-Ad Set/1
25.4806	green line® Mix-Ad Set/2
25.4808	green-line® Mix-Ad Set/1
25.4809	green line® Mix-Ad Set/1-R
25.4811	green line® Mix-Ad Set/2-R
25.4812	green line® Mix-Ad Set/2
25.4813	green line® CODAN Guard® Mix-Ad Set/1
25.4817	green line® Mix-Ad Set/1
37.2617	S86
37.2708	S86-R
37.2715	I86
37.2720	S86-R
37.2804	I86
37.3110	Needle-free SMS Primary Set
37.3133	LIGHT-SAFE S86
37.3137	B86
37.3138	B86
37.3143	SMS Primary Set
37.3156	S86
37.3159	S86-R
37.3160	S86
37.3179	B86

CODAN REF	Product Name / Produktname
37.3192	IVIP® 708/718 S86
37.3196	S86-R
37.3198	IVIP® 708/718 S86
37.3310	S86
37.3312	S86
37.4808	green line® B86
37.4812	green line® B86-R
37.4813	green line® IVIP® 708/718 B86
37.4816	green line® B86
37.4817	green line® S86
43.3030	L86
43.3900	CODAN Guard® V86
43.3902	CODAN Guard® V86
43.3903	CODAN Guard® V86-R
43.3905	CODAN Guard® V86-R
43.3906	CODAN Guard® V86-R
43.3909	CODAN Guard® V86-R
43.3911	green line® V86
43.3912	CODAN Guard® V86-R
43.3914	CODAN Guard® V86-R
43.3917	CODAN Guard® V86-R
43.3923	CODAN Guard® V86-R
43.3927	green line® CODAN Guard® L86
43.4233	V86
43.4237	LIGHT-SAFE L86
43.4240	V86-R
43.4252	V86
43.4255	V86-L
43.4262	CODAN Guard® V86
43.4264	V86
43.4270	V86
43.4321	V86
43.4333	V86-R
43.4341	V86-R



CODAN REF	Product Name / Produktname
43.4342	V86
43.4343	V86
43.4349	L86
43.4353	L86-R
43.4354	L86-R
43.4355	V86
43.4358	L86-R
43.4359	V86-R
43.4360	V86-R
43.4363	V86
43.4384	LIGHT-SAFE V86-MT
43.4401	V86-R I.V.STAR® 10
43.4417	L86-R
43.4434	L86
43.4435	V86
43.4438	L86
43.4440	V86
43.4443	L86
43.4457	V86-R
43.4460	V86 I.V.STAR® 10
43.4465	L86-R
43.4469	V86
43.4471	V86-R
43.4476	V86-R
43.4488	IVIP® 708/718 V86-R I.V.STAR® 10
43.4492	L86
43.4535	L86
43.4538	V86-R
43.4642	IVIP® B V86
43.4644	IVIP® B V86
43.4824	green line® LIGHT-SAFE L86
43.4825	green line® V86
43.4826	green line® V86
43.4829	green line® V86
43.4830	green line® IVIP® 708/718 V86

CODAN REF	Product Name / Produktname
43.4833	green line® V86-R
43.4836	green line® V86-MT
43.4837	green line® V86-MT
43.4840	green line® IVIP® 708/718 V86 I.V.STAR® 10
43.4841	green line® L86
43.4842	green line® L86
43.4844	green line® L86-R
43.4845	green line® L86-R
43.4846	green line® V86-R I.V.STAR® 10
43.4854	green line® V86-R
43.4860	green line® L86-R
43.4864	green line® LIGHT-SAFE IVIP® 708/718 V86
43.4870	green line® L86-R
43.4871	green line® L86-R
43.4877	green line® L86-R
43.4975	L86
43.4980	IVIP® 708/718 V86
43.4982	IVIP® 708/718 V86
43.5002	L86
43.5075	L86
43.5105	V86
43.5110	L86-MT
43.5126	L86
43.5130	L86
43.5139	V86
43.5140	V86
43.5141	V86
43.5144	V86
43.5152	V86
43.5157	V86
44.2129	E30-R MF-5 I.V.STAR® PLUS 10
53.1007	Y-I86/2
71.4102	LIGHT-SAFE E09 MF-3 I.V.STAR® PLUS 10
71.4544	E30-R I.V.STAR® 10

CODAN REF	Product Name / Produktname
71.4834	green line® E30 I.V.STAR® 10
72.3158	C09/2-R I.V.STAR® 1,6
72.3178	C09/2-R SWAN-LOCK® I.V.STAR® 1,6
72.3189	TPN System Neo/Paed I.V.STAR® 1,6
72.3190	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® F 1,6
72.3196	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® F 4,5
72.3197	TPN System Neo/Paed I.V.STAR® 4,5
76.3112	E30-R I.V.STAR® 10
76.3274	E25 MF-5 I.V.STAR® 10
76.3297	E25 MF-5 I.V.STAR® 10
76.3302	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® 1,6
76.3320	V86
76.3325	S86
76.3335	S86
76.3348	V86
76.3373	LIGHT-SAFE TPN System Neo/Paed
76.3379	TPN System Neo/Paed
76.3384	Drip SWAN® I99
76.3387	Cyto-Ad Z®/4-L I.V.STAR® 10
76.3392	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® 1,6
76.3393	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® 1,6
76.3395	Cyto-Ad Z®/4
76.3396	TPN System Neo/Paed I.V.STAR® 1,6
76.3399	TPN System Neo/Paed I.V.STAR® 1,6
76.3408	TPN System Neo/Paed I.V.STAR® 1,6
76.3412	Cyto-Ad-Wing Z®/4
76.3414	IVIP® B Cyto-Ad-Wing Z®/2
76.3416	IVIP® B Cyto-Ad-Wing Z®/4
76.3417	LIGHT-SAFE E09-R SWAN-LOCK® I.V.STAR® F 1,6
76.3418	Cyto-Ad-Wing Z®/4
76.3419	Cyto-Ad-Wing Z®/4
76.3420	Cyto-Ad-Wing Z®/2
76.3421	Cyto-Ad-Wing Z®/4

CODAN REF	Product Name / Produktname
76.3422	Cyto-Ad-Wing Z®/1
76.3423	B86-R
76.3425	Cyto-Ad-Wing Z®/4
76.3434	Cyto-Ad-Wing Z®/4
76.3436	Cyto-Ad-Wing Z®/2
76.3437	Cyto-Ad-Wing Z®/4
76.3440	Cyto-Ad-Wing Z®/2
76.3443	Cyto-Ad-Wing Z®/2
76.3444	Cyto-Ad-Wing Z®/6
76.3445	Cyto-Ad-Wing Z®/4
76.3446	Cyto-Ad-Wing Z®/2
76.3447	Cyto-Ad-Wing Z®/1
76.3450	Cyto-Ad-Wing Z®/2
76.3452	E25-R I.V.STAR® 10
76.3453	Cyto-Ad-Wing Z®/1 I.V.STAR® 10
76.3454	Cyto-Ad-Wing Z®/1
76.3455	Cyto-Ad-Wing Z®/1
76.3456	Cyto-Ad-Wing Z®/2
76.3457	Cyto-Ad-Wing Z®/4
76.3458	TPN System Neo/Paed I.V.STAR® 1,6
76.3459	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® F 1,6
76.3461	Cyto-Ad-Wing Z®/1 I.V.STAR® 10
76.3463	IVIP® B2 Cyto-Ad-Wing Z®/4
76.3464	IVIP® B2 Cyto-Ad Z®/1-L I.V.STAR® 10
76.3465	IVIP® B2 Cyto-Ad-Wing Z®/2
76.3466	IVIP® B2 V86
76.3467	IVIP® B2 Cyto-Ad Z®/1
76.3468	IVIP® B2 Cyto-Ad Z®/2
76.3469	IVIP® B2 Cyto-Ad Z®/4
76.3470	IVIP® B2 Cyto-Ad-Wing Z®/4
76.3471	IVIP® B2 Cyto-Ad-Wing Z®/6
76.3472	green line® IVIP® B2 Cyto-Ad-Wing Z®/2
76.3473	green line® IVIP® B2 Cyto-Ad-Wing Z®/4
76.3474	green line® IVIP® B2 Cyto-Ad-Wing Z®/6
76.3475	IVIP® B2 Cyto-Ad-Wing Z®/2-L I.V.STAR® 10

CODAN REF	Product Name / Produktname
76.3520	Drip SWAN® I99-R
76.3521	Drip SWAN® I99
76.3522	Drip SWAN® I99-R
76.3523	Drip SWAN® I99-R
76.3524	Drip SWAN® I99-R
76.3525	Drip SWAN® I99
76.3526	Drip SWAN® I99-R
76.3527	Drip SWAN® I99-R
76.3528	Drip SWAN® I99-R
76.3529	Drip SWAN® I99-R
76.3532	Drip SWAN® Y-I99/2
76.3533	Y-I99/2-R
76.3534	Drip SWAN® I99-R
76.3535	Drip SWAN® I99 I.V.STAR® 10
76.3554	Cyto-Ad Z®/1-L I.V.STAR® 10
76.3555	I99-R
76.3601	CODAN Guard® Y-I86-WW/2
76.3606	Cyto-Ad Z®/1
76.3607	Cyto-Ad Z®/2
76.3608	Cyto-Ad Z®/4
76.3613	CODAN Guard® Y-I86-WW/3
76.3614	Y-I99-WW/3
76.3615	Y-I99/4
76.3616	Y-I86-WW/5
76.3619	IVIP® B Cyto-Ad Z®/4
76.3631	Y-I99/2
76.3634	Cyto-Ad Z®/4
76.3639	LIGHT-SAFE Cyto-Ad Z®/2
76.3642	Cyto-Ad Z®/4
76.3643	Cyto-Ad Z®/2
76.3644	Cyto-Ad Z®/1
76.3645	IVIP® B Cyto-Ad Z®/4
76.3646	IVIP® B Cyto-Ad Z®/1
76.3647	IVIP® B Cyto-Ad Z®/2
76.3650	Cyto-Ad Z® /4
76.3652	IVIP® B Cyto-Ad Z®/1-L
76.3653	IVIP® B Cyto-Ad Z®/4

CODAN REF	Product Name / Produktname
76.3654	IVIP® B Cyto-Ad Z®/2
76.3656	I86
76.3657	Y-I99-WW/4
76.3661	Cyto-Ad Z®/4
76.3663	Cyto-Ad-Wing Z®/4
76.3667	LIGHT-SAFE Cyto-Ad Z®/2
76.3668	LIGHT-SAFE Cyto-Ad Z®/4
76.3669	LIGHT-SAFE Cyto-Ad Z®/1
76.3673	Cyto-Ad-Wing Z®/4
76.3674	Cyto-Ad-Wing Z®/2
76.3680	Cyto-Ad-Wing Z®/2
76.3681	LIGHT-SAFE Cyto-Ad-Wing Z®/2
76.3682	LIGHT-SAFE Cyto-Ad-Wing Z®/4
76.3683	LIGHT-SAFE Cyto-Ad-Wing Z®/1
76.3687	LIGHT-SAFE Cyto-Ad Z®/1
76.3688	LIGHT-SAFE Cyto-Ad Z®/4
76.3689	Cyto-Ad-Wing Z®/4
76.3695	Cyto-Ad-Wing Z®/6
76.3701	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® 1,6
76.3702	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® 1,6
76.3703	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® 4,5
76.3704	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® 4,5
76.3706	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® PLUS 1,6
76.3707	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® 1,6
76.3708	LIGHT-SAFE E09 I.V.STAR® F 4,5
76.3709	LIGHT-SAFE E09-R I.V.STAR® 1,6
76.3719	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® 1,6
76.3720	LIGHT-SAFE TPN System Neo/Paed I.V.STAR® 4,5
76.3723	LIGHT-SAFE E09-R I.V.STAR® F 4,5
76.3900	CODAN Guard® Y-I86-WW/2
76.3904	CODAN Guard® I86-WW-Y/2
76.3905	CODAN Guard® I86-WW-Y/4
76.3907	CODAN Guard® Y-I86-WW/3
76.3908	CODAN Guard® Y-I86-WW/4
76.3909	CODAN Guard® Y-I86-WW/5



CODAN REF	Product Name / Produktname
76.3911	CODAN Guard® Y-I86-WV/3
76.3912	CODAN Guard® Y-I86-WV/4
76.3913	CODAN Guard® Y-I86-WV/5
76.3915	CODAN Guard® V86-R
76.3917	CODAN Guard® V86-R
76.3918	CODAN Guard® Y-I86-WV/2
76.3919	CODAN Guard® Y-I99-WV/2
76.3921	CODAN Guard® V86-R
76.3922	CODAN Guard® V86-R
76.3923	CODAN Guard® Drip SWAN® I99-R
76.3924	CODAN Guard® Drip SWAN® I99
76.3925	CODAN Guard® Drip SWAN® I99-R
76.3926	CODAN Guard® Drip SWAN® I99-R
76.3927	CODAN Guard® Drip SWAN® I99-R
76.3928	CODAN Guard® Drip SWAN® I99
76.3929	CODAN Guard® Drip SWAN® I99-R
76.3930	CODAN Guard® Drip SWAN® I99-R
76.3931	CODAN Guard® Drip SWAN® I99-R
76.3932	CODAN Guard® Drip SWAN® I99-R
76.3935	CODAN Guard® Drip SWAN® Y-I99/2
76.3936	CODAN Guard® Y-I99/2-R
76.3937	CODAN Guard® Drip SWAN® I99-R
76.3938	CODAN Guard® V86-R
76.4000	V86-R
76.4002	V86-R
76.4004	S86-R
76.4012	TIVA Set 2
76.4015	L86-R
76.4020	L86-R
76.4029	S86-R
76.4034	TIVA Set 2
76.4035	L86-R
76.4052	S86-R
76.4053	S86-R
76.4061	S86-R
76.4062	CODAN Guard® V86-R

CODAN REF	Product Name / Produktname
76.4435	B86-R I.V.STAR® 4,5
76.4784	green line® L86-R
76.4796	green line® B86-R
76.4826	green line® Cyto-Ad-Wing Z®/4
76.4845	green line® Cyto-Ad Z®/1
76.4846	green line® Cyto-Ad Z®/2
76.4847	green line® Cyto-Ad Z®/4
76.4848	green line® IVIP® 708/718 Cyto-Ad Z®/2
76.4849	green line® IVIP® 708/718 Cyto-Ad Z®/4
76.4862	green line® TIVA Set 2
76.4865	green line® TIVA Set 2
76.4881	green line® IVIP® 708/718 Cyto-Ad-Wing Z®/1
76.4882	green line® IVIP® 708/718 Cyto-Ad-Wing Z®/2
76.4883	green line® IVIP® 708/718 Cyto-Ad-Wing Z®/4
76.4891	green line® LIGHT-SAFE IVIP® 708/718 Cyto-Ad-Wing Z®/2
76.4892	green line® LIGHT-SAFE IVIP® 708/718 Cyto-Ad-Wing Z®/4
76.7500	Y-I99-WV/2
76.7506	Cyto-Ad-Wing Z®/2
76.7507	LIGHT-SAFE Cyto-Ad-Wing Z®/2
76.7508	LIGHT-SAFE Cyto-Ad-Wing Z®/4
76.7509	Cyto-Ad-Wing Z®/4
76.7511	LIGHT-SAFE IVIP® 708/718 Cyto-Ad-Wing Z®/2
76.7512	LIGHT-SAFE IVIP® 708/718 Cyto-Ad-Wing Z®/4