

B. Braun Melsungen AG Division Aesculap Vascular Systems

Sieversufer 8

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Internet:

http://www.bbraun.com

Date:

November 03, 2023

Your customer no.: [123456789]

2023-01

[Hospital] [Adress]

Our reference no.: FSCA-VS-

Urgent Field Safety Notice Combitrans® / Combidyn® Monitoring Sets Changes to the instructions for use

Dear customer,

You use one or more of the medical devices listed in Appendix 1 in your hospital.

Combitrans® / Combidyn® Monitoring Sets are invasive, disposable monitoring systems for measuring physiological blood pressure and blood sampling. They are supplied sterile and for single patient use.

As users already know, prolonged contact with organic solvents (spray disinfectants) can promote the formation of stress cracks in plastic tubing connectors and multidirectional stopcocks.

A corresponding warning for the Discofix multidirectional stopcocks integrated in the affected sets was already distributed by the manufacturer (see Appendix 2). However, it is not yet distributed with the sets as we were only recently informed about it by the manufacturer. We would therefore like to inform you that in the future the affected Combitrans® / Combidyn® monitoring sets will include also a separate warning notice for the Discofix multidirectional stopcocks.

Risk for the patient

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In extremely rare cases, stress cracks can lead to fluid leakage and the risk of an associated change in pressure signal transmission. Furthermore, air entry with the risk of an air embolism cannot be ruled out.

The risks mentioned in connection with leaky connections are generally known and are already listed in the current instructions for use:

"Risks: Potential complications include infection, embolism caused by air bubbles or blood clots, over-infusion or leakage. A leaking connection will allow air to enter the system and produce incorrect low pressure readings. (...) Furthermore, air bubbles may have a negative effect on the pressure reading. Air bubbles should carefully be removed from the flush reservoir and tubing to prevent any air bubbles from entering the transducer."

Measure by B. Braun Melsungen AG

In order to further reduce the actual occurrence of these risks, the instructions for use will contain a corresponding additional note in the future:

"Multidirectional stopcocks and tubing connections may tend to crack formation when influenced with alcohol-based disinfectants. These cracks can result in leaks or air ingress. We recommend inspecting the entire infusion line for these hazards."

Due to a requirement from the manufacturer of the Discofix multidirectional stopcock, the products listed in Appendix 1 will contain an additional separate warning (see Appendix 2).

Recommended measures until the new instructions for use are available

- If components of the Combitrans® / Combidyn® monitoring system are being disinfected in your hospital, please pay attention to the formation of stress cracks in tubing connections and multidirectional stopcocks during further use.
- 2) If you notice stress cracks and/or fluid leakage, please change the entire monitoring system.
- 3) If you require further information on correct product use or training, please contact your responsible B. Braun sales representative. They will contact you and provide you with the information you require.
- 4) Please ensure that all users of the above-mentioned products and other persons to be informed are informed of this urgent safety information. If you have given the products to third parties, please forward a copy of this information to them.

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- 5) Please note the warning notice for the Discofix® multidirectional stopcock (Appendix 2).
- 6) Please confirm receipt of the Field safety notice on the enclosed form (Appendix 3).

B. Braun Melsungen AG - Vascular Systems has informed the Federal Institute for Drugs and Medical Devices (BfArM) about the distribution of this urgent safety information.

We apologize for any inconvenience this may cause you. If you have any questions, please do not hesitate to call us on +49 30 568207-120 or contact us at vigilance-vs@bbraun.com. Thank you very much in advance for your understanding and support.

B. Braun Melsungen AG i.A.

i.V.



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Annex 1

REF no.	Product name			
5010244	SET POUR CHAMBRE IMPLANTABLE			
5010741	HAEMOFIX-COMBITRANS CBSS MONO CARCHIR			
5011297	COMBITRANS SET ARTERIELL MIT BEH			
5011298	COMBITRANS-SET 2-FACH BEH			
	CONTRAST / PRESSURE SYSTEM WITH			
5012707	SYRINGE			
5012875	MITRA - SET KARLSBURG			
5012943	MITRACLIP-SET ROBERT-BOSCH-KH			
5013116	ADD ON INFUSIONSSET KSSP AARAU			
5013302	MITRACLIP-SET UMR			
5013583	MITRA CLIP SET BAD ROTHENFELDE			
5014530	MITRACLIP SET CKU			
5017392	INFUSIONSSET KLINIKUM OLDENBURG			
5017833	ARTERIEN SET BOCHUM			
5018353	COMBITRANS KIT PAED			
5018642	INFUSIONSLEITUNG MIT DWH 250 CM			
5018686	ARTERIOFI SET 22G/80MM Hubertus Ber- lin			
5019603	MONITORING-SET HKL HOMBURG			
5019764	SET CT AN. CRÈAT.18G VERT CL.GENOLIER SA			
5019765	CT AN.CRÈAT. 20G ROSE GRENOLIER LAUSANNE			
5019766	Set IRM, CLINIQUE DE GENOLIER SA			
5019767	SET PET-CT (CLINIQUE DE GENOLIER SA)			
5200004	COMBITRANS-SET HERZ-LUNGEN- MASCHINE			
5200010	COMBITRANS 1-FACH MONITORING-SET			
5200011	COMBITRANS 2-FACH MONITORING SET			
5200031	EXADYN MONITORING SET			
5200032	COMBITRANS MONITORING SET 2-FACH HELIOS			
5200033	COMBITRANS MONITORING SET 3-FACH			
5200034	COMBITRANS MONITORING SET HELIOS			
5200040	COMBITRANS ROYAL NORTH SHORE HOSPITAL			
5200050	HÄMOFIX CM EXADYN SET BAD HERSFELD			
5200059	SET V3 LA FE			
5200181	HAEMOFIX-MONITORING-SET 2-FACH, BEH			
5200182	HAEMOFIX-MONITORING-SET ARTERIELL, BEH			

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REF no.	Product name		
5209127	SPECIAL ARTERIAL MONITORING SET		
5209135	SPECIAL CVP MONITORING SET		
5209302	COMBITRANS MONITORING SET HAMBURG		
5209364	COMBITRANS-EWT, BLAU		
5209466	COMBITRANS-EWT, GELB		
5209922	COMBITRANS HÄMOFIX MONITORING SET 3-FACH		
5210044	COMBITRANS MONITORING SET 2-FACH PLUS		
5210050	COMBITRANS-SET, KH STUTTGART		
5210055	COMBITRANS ZUBEHOER SET		
5210152	CMS ST.JOSEF KH SCHWEINFURT		
5210349	COMBITRANS HAEMOFIX EXADYN MIT BEH		
5210521	SCHANZER EXADYN SET OP_49 A_49 C		
5210522	SCHANZER COMBITRANS SET 49 I		
5210561	COMBITRANS-MONITORING-SET		
5210571	COMBITRANS-MONITORING-SET		
5210865	HAEMOFIX COMBITRANS SET ARTERIELL		
5210976	COMBITRANS MONITORING-SET		
5211090	HAEMOFIX 2-FACH COMBITRANS SET		
5211110	COMBITRANS-SET ARTERIELL,PAEDIATRIE		
5211247	COMBITRANS MONITORING-SET		
5211298	COMBIDYN-Set		
5211700	COMBITRANS MONITORING-SET, PVC-		
5212021	ADD ON SET HAEMOFIX ROT 2,4 ml		
5212033	COMBITRANS MONITORING SET VENOES UNI HRO		
5212045	COMBITRANS MONITORING SET WEHNER		
5212055	EXADYN COMBITRANS DRUCKMESS-SET 202-1307		
5212391	EXADYN-COMBITRANS PVC-FREI		
5212782	COMBITRANS MONITORING PAEDIATRIE- SET VIL		
5212795	EXADYN SET MIT BEH KL. ESSLINGEN		
5212847	COMBITRANS-MONITORING-SET		
5213256	HAEMOFIX EXADYN SET BAD HERSFELD II		
5213330	EXADYN-MONITORING-SET PAEDIATRIE		
5213460	COMBITRANS-MONITORING-SET		

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REF no.	Product name		
5200183	HAEMOFIX-MONITORING-SET ART/VEN BEH		
5200184	HAEMOFIX EXADYN SET LANGE LEITUNGEN		
5200253	SET PIC V1 LA FE		
5200294	ARTERIOFI-SET FEMORAL CHEMNITZ		
5200359	ADD ON MIT BEH		
5200393	COMBITRANS-MONITORING-SET, ROT		
5200427	COMBITRANS ARTERIELL KL.NEUMARKT OPF.		
5200458	COMBITRANS-EXADYN SAFESET 200CM		
5200671	ANTI-SHUNT-COMBITRANS MONITORING- SET ART		
5200686	DRUCKDOM-SET OHNE COMBIDYN		
5200809	COMBITRANS MONITORING SET, ROT		
5200830	COMBITRANS MONITORING-SET 2-FACH		
5200849	COMBITRANS MONITORING-SET 3-FACH		
5200872	COMBIDYN MONITORING KIT WITH PRESSURE DO		
5200880	COMBITRANS EC HLM WIEN		
5201024	COMBITRANS SET PAEDIATRIE		
5201025	UKE SET EINFACH ART/VEN GBE		
5201030	UKE SET ZWEIFACH ART/VEN GBE		
5201035	COMBITRANS UKE 3-FACH BES		
5201120	ART/VEN DRUCKMESSSYSTEM 2- TRANSDUCER H9		
5201130	ART/VEN DRUCKMESSSYSTEM 1- TRANSDUCER		
5201152	COMBITRANS MONITORING-SET 2-FACH		
5201209	COMBITRANS ARTERIELL.PEAD SET FREIBURG		
5201406	COMBITRANS EC DRUCKMESSSET 3- FACH		
5201428	CMS HÄMOFIX BEH 2-FACH PLUS		
5201432	ADD-ON-SET HÄMOFIX BLAU		
5201493	CTBK SDL + CTA		
5201500	COMBIDYN SPUELSYSTEM 3ML/H		
5201667	COMBITRANS 2-FACH SET MOD.I UNI GIESSEN		
5201675	COMBITRANS 1-FACH SET MOD.II UNI GIESSEN		
5201819	HAEMOFIX EXADYN SET (1 ENTNAHMEPORTS)		
5202018	Combitrans Haemofix EVK		
5202022	COMBITRANS-SET SCHULTHESSKL. ZUERICH		

DEC	Dungdy of many a	
REF no.	Product name	
5213505	HAEMOFIX-COMBITRANS MONITORING-	
	SET ARTER	
5213516	HAEMOFIX-EXADYN MONITORING-SET	
	ART. + VE HAEMOFIX-COMBITRANS MONITORING-	
5213527		
E01/010	SET 2-FAC	
5214010	COMBITRANS SET ROT ESSEN	
5214020	COMBITRANS SET BLAU ESSEN	
5214040	HAEMOFIX-COMBITRANS SET 2-FACH BEH 4,8ML	
5214076	COMBITRANS-SET BAD WILDUNGEN	
5214271	EXADYN-COMBITRANS-MS	
5214319	CMS-LEOPOLD.KH SCHWEINFURT	
3214317	MED.ITS	
5214335	COMBITRANS-MONITORING-SET 1-FACH	
5214378	COMBITRANS SET 2-FACH PLUS	
5214433	COMBITRANS SET ARTERIELL MIT BEH	
5214580	COMBITRANS-MS +1+ UNI MD HTC AN	
E01//07	CMS LEOPOLDINA KH SCHWEINFURT	
5214637	ANÄSTOP	
5214700	COMBITRANS-MONITORING-SET 1-FACH,	
3214700	JENA	
5214777	EXADYN-COMBITRANS-MONITORING-SET	
3214///	AUGSBG.	
5214807	COMBITRANS-HIRNDRUCK-SET. JENA	
5214884	COMBITRANS SET EXADYN VBW	
5215013	COMBITRANS MONSET ST.GALLEN I.	
5215050	HAEMOFIX-COMBITRANS SET 3-FACH BEH 4,8ML	
5215300	COMBITRANS EXADYN SET MODELL F.	
5215454	HAEMOFIX COMBITRANS SET ARTERIELL 4,8ML	
5215514	EXADYN SET KLINIKUM MITTELBADEN	
5215555	HAEMOFIX-EXADYN SET BEH 4,8 ML	
5215859	Hämofix-CMS Set 2-fach, BEH art. + ven.	
5216200	COMBITRANS MONITORING-SET KLETTBAND	
5217857	TYKS PRESSURE KIT	
5218347	COMBITRANS SET PS MAGDEBURG	
E010500	COMBIDYN DRUCKSCHL.M. DWH ROT 15	
5218598	CM PE	
5218655	HAEMOFIX-EXADYN-SET ST. GALLEN	
5219208	COMBITRANS SET MIT ENTNAHMEHAHN	
5219525	CMS SET 3-FACH PLUS ZYPERN	
5219730	DRUCKMESS-SET-NOTTWIL	

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REF no.	Product name			
5202024	COMBITRANS-SET SCHULTHESSKL.			
3202024	ZUERICH 2-F			
5202059	COMBITRANS KINDER SET FULDA			
5202088	ITS HAEMOFIX BEH SET			
5202115	INTRAFI ASSEMBLY SWEDEN			
5202124	COMBITRANS SET LATEX/PVC FREI- OLGAHOSPIT			
5202286	COMBITRANS-SET INTENSIV SCHWARZWALD BAAR			
5202407	COMBITRANS HAEMOFIX ARTERIELL 2,4ML BEH			
5202408	COMBITRANS EXADYN HAEMOFIX 2,4ML BEH			
5202409	COMBITRANS 2-FACH HAEMOFIX 2,4ML BEH			
5202500	COMBITRANS MS 2+ UNI MD			
5202507	EXADYN-COMBITRANS MONITORING-SET			
5202604	COMBITRANS MONITORING-SET VENOES			
5202614	COMBITRANS-MONITORING-SET VENOUS LONG			
5202617	COMBITRANS MONITORING-SET PULMONALARTERI			
5202620	COMBITRANS MONITORING-SET ARTERIELL			
5202706	CTBK SDL + CTV			
5202766	HÄMOFIX CM SET DIAKONIE KL. KASSEL			
5203032	HLM SET BEAU SITE 2			
5203033	COMBITRANS UKE EXADYN			
5203034	COMBITRANS UKE 1-FACH ARTERIELL			
5203036	COMBITRANS UKE 3-FACH			
5203037	COMBITRANS PA ALBERTINEN HH			
5203041	COMBITRANS UKE 1-FACH ERGAENZUNG			
5203043	SET DOUBLE Q-6 10.150			
5203044	COMBITRANS PÄDIATRIESET KL. AMBERG			
5203111	COMBITRANS MONITORING KIT PAEDIATRIC			
5203567	NOTFALLSET			
5203579	Combitrans ITS-Set Meppen			
5203611	COMBITRANS-SET 2-FACH PLUS REGENSBURG			
5203617	COMBITRANS EC HAEMOFIX BAD HERSFELD II			
5203633	COMBITRANS-SET 3-FACH PLUS REGENSBURG			
5203644	COMBITRANS ADD-ON-SET WEISS			

REF no.	Product name		
5231999	COMBITRANS 2-FACH ADD ON HCI ESSEI		
5311010	COMBITRANS EC TYP MUENCHEN ARTERIELL		
	COMBITRANS EC HÄMOFIX-EXADYN SET		
5311325	MIT BEH		
5311630	Double CMS EC Set (ART/CVP/Add-ON)		
5311631	SINGLE CMS EC SET		
5311632	ADD-ON CMS-EC SET		
5311633	DREIFACH CMS-EC SET (ART/CVP/LAP/ADD-ON)		
5312020	COMBITRANS EC TYP MUENCHEN VENOES		
5313030	COMBITRANS EC TYP STUTTGART		
5313720	COMBITRANS EC HAEMOFIX 2-FACH PLUS		
5313730	COMBITRANS EC HAEMOFIX 3-FACH PLUS		
5318575	COMBITRANS EC EXADYN SET		
5318765	COMBITRANS-EC ADD ON PAP		
5318768	COMBITRANS-EC UKE 3-FACH		
5318776	COMBITRANS MONITORING EC ADD ON SET		
5319280	COMBITRANS EC HLM HZ KARLSBURG		
5319289	COMBITRANS EC ARTERIELL		
5319290	COMBITRANS EC VENÖS		
5319291	COMBITRANS EC ART/BEH		
5319292	COMBITRANS EC ART+VEN / BEH		
5319295	CEC HAEMOFIX SET ARTERIELL BEH		
5319300	CEC HAEMOFIX-EXADYN SET		
5319305	COMBITRANS EC MIT BEH		
5319310	CMS EC 1-FACH ARTERIELL OHNE RESERVOIR		
5319311	CMS CT-EC 2-FACH OHNE RESERVOIR		
5319312	CMS EC ADD-ON PAP - GELB		
5319315	CMS EC ADD-ON WEISS		
5319553	COMBITRANS EC HÄMOFIX SET HKZ ROTENBURG		
5440001	COMBITRANS ART/VEN GBE 4,8 PRO BEH		
5440003	COMBITRANS ART/VEN PLUS BBE 4,8 PRO BEH		
5440004	COMBITRANS SET BAD NEUSTADT		
5660040	ZVK SET CHARITÉ		

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REF no.	Product name			
5203647	CT 3FACH BEH AUGUSTA BOCHUM			
5203653	CMS MONITORING SET ARTERIELL HIRSLANDEN			
5203654	CMS MONITORING SET 2-FACH HIRSLANDEN			
5203655	COMBITRANS SET ARTERIELL			
E202/E/	CMS MONITORING SET 3-FACH			
5203656	HIRSLANDEN			
5203666	HAEMOFIX-BAUGRUPPE			
5203677	HAEMOFIX COMBITRANS SET ARTERIELL			
5203688	COMBITRANS ADD-ON-SET GELB			
5204030	COMBITRANS-SET 3 1/2-FACH			
5204332	COMBITRANS VEN.PAED.SET UNI FREIBURG			
5204604	MONITORING SET-2FACH HTG UNI JENA			
5204781	HAEMOFIX SET TICINO			
5205022	DOUBLE MONIT.SET (ART/CVP/ADD-ON)			
5205117	COMBIDYN LEITUNG M/M, ROT, 200 CM			
5205581	COMBIDYN-SET EV.JOHANN.DUISBURG			
5205689	COMBIDYN MONITORING SET OHNE DRUCKDOM			
5205848	EXADYN-MONITORING-SET KL. DRESDEN			
5205850	COMBITRANS HIRNDRUCKMESS SET DRESDEN			
5206000	COMBITRANS 1-FACH MIT BEH/HAEMOFIX			
5206011	COMBITRANSSET LUND 1-LINJE ARTAER			
5206066	COMBITRANSSET LUND 2-LINJE			
5206100	COMBITRANS ADD ON PAP			
5206131	MHH ADD ON NACH DR.GRAS			
5206482	COMBITRANS-SET 2-FACH HÄMOFIX BEH KS ZUG			
5206530	COMBITRANS HÄMOFIX SINGLE KS ZUG			
5206610	Combitrans 2fach R.B.KH HerzOP GBE			
5206620	ART/VEN DRUCKMESSSYSTEM 2- TRANSD. H9 GBE			
5206630	ART/VEN DRUCKMESSSYSTEM 1- TRANSDUCER GBE			
5206767	COMBITRANS SET 1-FACH ZVD MIT BEH/HA			
5206831	COMBITRANS-SET KS ZUG			
5206988	HAEMOFIX SET BRANDENBURG			
5206994	EXADYN-MONITORING-SET(LANGE LEITUNGEN)			
5207032	COMBITRANS SET 4-FACH DUESSELDORF			
5207051	COMBITRANS-SET 3-FACH UNI MUENSTER			
5207069	COMBITRANS MONITORING SET			

REF no.	Product name		
5770001	COMBIDYN PVC 20 CM M.DISCOFIX PLUS ROT		
5770002	COMBIDYN PVC 20 CM M.DISCOFIX PLUS BLAU		
5770003	COMBIDYN PVC 20 CM M.DISCOFIX PLUS WEISS		
5770027	ERGAENZUNGSSET SIEGBURG		
5770038	DRUCKMESSSET FUER NEONATOLOGIE		
5770063	COMBITRANS ART / VEN HF BEH		
5770064	COMBITRANS ART HF BEH		
5770093	COMBITRANS 3 PLUS HELIOS HZ KA		
5770104	COMBITRANS 2 PLUS GBE ROTES RES. HZL		
5770533	COMBITRANS 1 BEH KLAR HZL		
5770543	COMBITRANS 2 GBE HZL		
5770544	COMBITRANS 1 GBE ROT HZL		
5770545	COMBITRANS 1 PA ADD ON HZL		
5770546	COMBITRANS 2 PLUS GBE HZL		
5770586	COMBITRANS ARTERIELL EPU HZ LEIPZIG		
5770599	DRUCKMESSSET NEONATOLOGIE NEU		
5771551	COMBITRANS-SET HERZ-LUNGEN- MASCHINE		
5771734	COMBITRANS-SET ARTERIELL		
5880001	SANA ADD-ON MIT BEH		
5880004	SANA 1-FACH ZVD MIT BEH/HAEMOFIX		
5880007	COMBITRANS 1-FACH MIT BEH/HAEMOFIX		
5880009	SANA 2-FACH MIT BEH UND HAEMOFIX		
5880012	CT PÄDIATRIE SET SANA		
5880100	SANA 1-FACH ART/VEN MIT BEH/HAEMOFIX/OP		
5880105	SANA 3-FACH MIT BEH/HAEMOFIX/OP		
5880110	SANA 1-FACH ARTERIELL BEH/ HAEMOFIX/OP		
5880115	SANA 2-FACH MIT BEH/HAEMOFIX/OP		
5880120	SANA 3-FACH MIT BEH/HAEMOFIX		
5880125	SANA HZ DRESDEN COMBITRANS 4- FACH		
5880130	SANA COMBITRANS SET 3-FACH OP		
5880135	SANA COMBITRANS SET 2-FACH OP		
5880140	SANA COMBITRANS SET ART/VEN - OP		
5880145	SANA COMBITRANS SET ARTERIELL OP		
489 7002 A	PROSET VORBEREITUNGSSET ZVK		
489849 7 A	PROSET VORBEREITUNGSSET ZVK		

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REF no.	Product name			
5207080	COMBITRANS MS, 2-FACH			
5207167	COMBITRANS MONITORING SET ADD-ON			
5207410	COMBIDYN MONITORING SET SENSONOR 840			
5207466	FRÜHGEBORENEN SET FRANZISKUS MÜNSTER			
5207590	SET V4 LA FE (COMBITRANS)			
5207710	COMBIDYN-DRUCKMESS-SET MODELL UKB			
5207722	COMBITRANS 2-FACH ROBERT-BOSCH- KH HERZOP			
5207730	COMBITRANS-SET MODELL MUENCHEN, VENOES			
5207744	COMBITRANS ADD-ON-SET BOSCH-KH HERZOP			
5207902	COMBITRANS SET V.R.2			
5208291	COMBITRANS 3-FACH HAEMOFI BEH			
5208388	HAEMOFIX-COMBITRANS-SET 2-FACH			
5208525	HAEMOFIX-COMBITRANS TRIPLE SET S.CAMILLO			
5208575	COMBITRANS EXADYN SET M.ENTNAHMEHAHN			
5208599	COMBIDYN DRUCKSCHL.MIT DWH ROT/20CM PVC			
5208706	IABP-Set, Kssp.St.Gallen			
5208800	COMBITRANS SET ART/VEN MIT BEH			
5209000	COMBITRANS SINGLE KIT (1)			
5209011	COMBITRANS MONITORING SET ARTERIELL			
5209012	COMBITRANS MONITORING SET ARTERIELL BEH			
5209022	COMBITRANS MONITORING SET VENOES			
5209060	COMBITRANS DOUBLE KIT			
5209090	COMBITRANS TRIPLE KIT			
5209092	COMBITRANS EXADYN SET			

REF no.	Product name		
4899061A	PROSET VORBEREITUNGSSET ZVK		
5200830M	COMBITRANS MONITORING SET 2-FACH		
5202507-1	EADYN-COMBITRANS MONITORING-SET CHILE		
78226F	ZVK-KIT UNIVERSITAETSKLINIK KIEL		
PL4000088	Combitrans Safe Set		
PL4000107	ABLAUF 300CM FÜR TROPF		
PL4000116	SET ZUR DRUCKMESSUNG SENSONOR 844		
PL4000144	COMBITRANS UMWANDLER, EINFACH		
PL4000222	SCHENKELARTHROSKOPIE SET FUER PRZEMYSL		
PL4000239	COMBITRANS&COMBIDYN SET FUER IBP MESSUNG		
PL4000284	SET FUER DRUCKMESSUNG, MIT DOM		
PL4000323	COMBITRANS SET		
PL4000366	MONITORING SET 1-FACH		
PL4000367	MONITORING SET 2-FACH		
PL4000368	MONITORING SET 2-FACH		
PL4000384	COMBITRANS VENÖS		
PL4000395	COMBITRANS ARTERIELL		
PL4000425	SET COMBITRANS		
PL4000427	COMBITRANS ARTERIELL		
PL4000430	COMBITRANS EC		
PL4000449	COMBITRANS ARTERIELL ŚW. RAFAŁ KRAKÓW		
PL4000468	SET FÜR SENSOR 844		
PL4000471	COMBITRANS TETNICZO-ŻYLNY		
PL4000482	COMBITRANS UMWANDLER, EINFACH 150 cm		

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Appendix 2

Discofix Warning Notice

See separately attached document "15328312_Discofix_A3_IFU_0520"

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Confirmation of the receipt of the Field Safety Notice for Combitrans® / Combidyn® Monitoring Sets from November 3rd, 2023

Ref. no. FSCA-VS-2023-01

Please return this completed form by email back to the following email address immediately, even if you no longer have any of the listed products:

Name:			
Position:			
Hospital:			
Address:			
Country:			
We hereby (confirm receipt of this info	rmation.	
			Cinn altura
		Date	Signature