

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

Dixion Vertrieb medizinischer Geräte GmbH
Couvenstr. 6
40211 Düsseldorf
Germany

for the scope

**electrocardiographs, patient monitors, modular patient monitors, fetal monitors,
ventilators, anesthesia machines, medical air compressors, medical suction units,
phototherapy lamps, infant incubators, open radiant infant warmer, syringe pumps,
infusion pumps, pulse oximeter, central monitoring station software
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2019-09-11
Valid until	2024-05-26
Registration no.	D1251600046
Report no.	P19-00612-156122
Stuttgart	2019-09-11



Head of Certification Body



mdc medical device certification GmbH
Kriegerstraße 6
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Attachment of the certificate

No. D1251600046

Date 2019-09-11

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Product category	Product	Class	Product code
anesthesia machines	Practice 3000 Practice 3100 Practice 3200 Practice 3700 Practice 3800	IIb	10-134
medical suction units	Vacus 7032 Vacus 7209	IIa	10-208
	Vacus 7305 Vacus 7308	IIa	10-217
medical air compressors	Dixon C34	IIb	10-972
electrocardiographs	ECG 1003	IIa	11-411
infant incubator	BabyGuard I-1103 BabyGuard I-1107 BabyGuard I-1120 BabyGuard I-1125	IIb	12-113
fetal monitors	Overtone 6200 Overtone 6900 Overtone 6900 lite Overtone 6900 Exp.	IIb	12-610
modular patient monitors	Storm D2 Storm D3 Storm D5 Storm D8 Storm DS3 Storm DS5 Storm DS7	IIb	12-636
patient monitors	Storm 5300 Storm 5500 Storm 5600 Storm 5800 Storm 5900 Storm 5110 Storm 5120	IIb	12-636



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Product category	Product	Class	Product code
syringe pumps	Instilar 1428	IIb	13-217
open radiant infant warmer	BabyGuard W-1140 BabyGuard W-1140-02 BabyGuard W-1145	IIb	13-250
pulse oximeter	Storm 5100	IIb	17-148
ventilators	Aeros 4300 Aeros 4300s Aeros 4500	IIb	17-423
	Aeros 4600 Aeros 4800	IIb	17-429
phototherapy lamps	BabyGuard U-1131 BabyGuard U-1133	IIa	17-515
central monitoring station software	CMS	IIb	17-588



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