

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	2021-01-07
Valid until	2024-05-26
Registration no.	D1251600051
Report no.	P20-01826-190522
Stuttgart	2021-01-07

Head of Certification Body



Attachment of the certificate

No. D1251600051

Date 2021-01-07

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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
electrocardiographs	ECG 1003 ECG 1003p. ECG 1012 ECG 1012Exp. ECG 1018	IIa	11-411
patient monitors	Storm 5300 Storm 5500 Storm 5600 Storm 5800 Storm 5900 Storm 5110 Storm 5120 Storm 5500A Storm 5500B Storm 5600A Storm 5600B	IIb	12-636
modular patient monitors	Storm D2 Storm D3 Storm D5 Storm D8 Storm DS3 Storm DS5 Storm DS7	IIb	12-636
fetal monitors	Overtone 6200 Overtone 6900 Overtone 6900 lite Overtone 6900 Exp.	IIb	12-610



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Product category	Product	Class	Product code
ventilators	Aeros 4300 Aeros 4300s Aeros 4500	IIb	17-423
ventilators	Aeros 4600 Aeros 4800	IIb	17-429
Medical air compressors	Dixon C34	IIb	10-972
medical suction units	Vacus 7209	IIa	10-208
phototherapy lamps	BabyGuard U-1131 BabyGuard U-1133	IIa	17-515
infant incubator	BabyGuard I-1103 BabyGuard I-1107 BabyGuard I-1120 BabyGuard I-1125	IIb	12-113
open radiant infant warmer	BabyGuard W-1140 BabyGuard W-1140-02 BabyGuard W-1145	IIb	13-250
syringe pumps	Instilar 1428 Instilar 1450 Instilar 1450 Pro	IIb	13-217
infusion pump	Instilar 1410 Instilar 1420 Instilar 1550 Instilar 1550 Pro	IIb	13-215
pulse oximeter	Storm 5100	IIb	17-148
central monitoring station software	CMS	IIb	17-588



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