

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that



**EKU Elektronik GmbH**  
**Am Sportplatz**  
**56291 Leiningen**  
**Germany**

for the scope

**anaesthesia units, workstations and monitors,  
electronic gas mixer, dosing units for therapy gases  
(see annex)**

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	2012-05-16
Valid until	2017-04-26
Registration no.	0157.02.21/0
Report no.	E 0157.02 / 2012-05-16
Stuttgart	2012-05-16

Head of Certification Body



**Annex of the certificate**

**No. 0157.02.21/0**      dated 2012-05-16

product	UMDNS	risk class			
		I	IIa	IIb	III
volume monitor			X		
multifunctional anaesthesia monitor			X		
mobile anaesthesia workstation				X	
anaesthetic ventilator	10-145			X	
volume-pressure-oxygen monitor	12-863		X		
electronic gas mixer				X	
anaesthesia workstation				X	
monitors for measuring, display and supervision of NIBP, SpO <sub>2</sub> and pulse			X		
modular system for anaesthesia workstation				X	
xenon-option	14-467			X	
dosing unit for therapy gas				X	



Head of Certification Body

