



Declaration of Conformity

GS Elektromedizinische Geräte G. Stemple GmbH

Hauswiesenstraße 26
86916 Kaufering

Germany

Product name	Defibrillators with monitor
Technical Documentation Reference Number	10_003
DoC Version Number	#03

declares under its sole responsibility, that the product including the accessories listed in Appendix I, to which the declaration relates, fulfills the essential requirements according to Annex I of the **Directive 93/42/EEC** on Medical Devices. According to the risk class of the product the following conformity assessment has been carried out via the following conformity assessment routes:

Conformity Assessment Routes:

Risk Class I:	Annex VII
Risk Class Is:	Annex VII combined with Annex V *)
Risk Class Im:	Annex VII combined with Annex V *)
Risk Class IIa:	Annex II without (4) *)
Risk Class IIb:	Annex II without (4) *)
Risk Class III:	Annex II including (4) *)

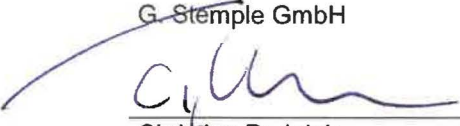
*) Notified Body	TÜV Süd Product Service GmbH Ridlerstraße 65, 80339 München, Germany
*) EC Certificate number(s)	G1 019931 0008 Rev. 01

Unless this Declaration of conformity is replaced by another Declaration of Conformity, this declaration is **valid until**

2024-05-26

Kaufering (Germany), 2021-05-25

GS Elektromedizinische Geräte
G. Stemple GmbH


Christian Podolak
Vice President Quality Management & Regulatory Affairs



Appendix I
Declaration of Conformity

Article no.	Description	Software Version (up to)	Risk class	GMDN Code	UMDNS Code	Remark
04000	Base model corpuls ³ consisting of: • 04100 • 04200 • 04300	4.x	IIb	17882	17-882	See subsequent positions
04100	Display Unit corpuls ³	4.x	IIb	17882	17-882	
04200	Patient Box corpuls ³	4.x	IIb	17882	17-882	
04300	Defib Unit corpuls ³	4.x	IIb	17882	17-882	
04000.1	NVG/ NVIS compatible consisting of: • 04100.1 • 04200.1 • 04300.1	4.x	IIb	17882	17-882	See subsequent positions
04100.1	Display Unit corpuls ³	4.x	IIb	17882	17-882	
04200.1	Patient Box corpuls ³	4.x	IIb	17882	17-882	
04300.1	Defib Unit corpuls ³	4.x	IIb	17882	17-882	
04000.2	HBO approved consisting of: • 04100.2 • 04200.2 • 04300.2	4.x	IIb	17882	17-882	See subsequent positions
04100.2	Display Unit corpuls ³	4.x	IIb	17882	17-882	
04200.2	Patient Box corpuls ³	4.x	IIb	17882	17-882	
04300.2	Defib Unit corpuls ³	4.x	IIb	17882	17-882	
04001	Base model corpuls ³ slim consisting of: • 04100 • 04200 • 04301	4.x	IIb	17882	17-882	See subsequent positions
04100	Display Unit corpuls ³	4.x	IIb	17882	17-882	
04200	Patient Box corpuls ³	4.x	IIb	17882	17-882	
04301	Defib corpuls ³ SLIM	4.x	IIb	17882	17-882	



Article no.	Description	Software Version (up to)	Risk class	GMDN Code	UMDNS Code	Remark
04002	Base model corpuls ³ Touch consisting of: • 04101 • 04201 • 04302	4.x	IIb	17882	17-882	See subsequent positions
04101	Display Unit corpuls ³ Touch	4.x	IIb	17882	17-882	
04201	Patient Box corpuls ³ Touch	4.x	IIb	17882	17-882	
04302	Defib corpuls ³ Touch SLIM	4.x	IIb	17882	17-882	
04003	Base model corpuls ³ MAX consisting of: • 04100 • 04200 • 04303	4.x	IIb	17882	17-882	See subsequent positions
04100	Display Unit corpuls ³	4.x	IIb	17882	17-882	
04200	Patient Box corpuls ³	4.x	IIb	17882	17-882	
04303	Defib corpuls ³ MAX	4.x	IIb	17882	17-882	
04003.1	NVG/ NVIS compatible consisting of: • 04100.1 • 04200.1 • 04303.1	4.x	IIb	17882	17-882	See subsequent positions
04100.1	Display Unit corpuls ³	4.x	IIb	17882	17-882	
04200.1	Patient Box corpuls ³	4.x	IIb	17882	17-882	
04303.1	Defib corpuls ³ MAX	4.x	IIb	17882	17-882	
04004	Base model corpuls ³ slim MAX consisting of: • 04100 • 04200 • 04304	4.x	IIb	17882	17-882	See subsequent positions
04100	Display Unit corpuls ³	4.x	IIb	17882	17-882	
04200	Patient Box corpuls ³	4.x	IIb	17882	17-882	
04304	Defib corpuls ³ SLIM MAX	4.x	IIb	17882	17-882	



Article no.	Description	Software Version (up to)	Risk class	GMDN Code	UMDNS Code	Remark
04005	Base model corpuls ³ Touch MAX [®] consisting of: • 04101 • 04201 • 04305	4.x	IIb	17882	17-882	See subsequent positions
04101	Display Unit corpuls ³ Touch	4.x	IIb	17882	17-882	
04201	Patient Box corpuls ³ Touch	4.x	IIb	17882	17-882	
04305	Defib corpuls ³ Touch SLIM MAX	4.x	IIb	17882	17-882	

Appendix II
Accessories intended by the manufacturer

Article no.	Description	Medical device (y/n)	Remarks
-/-	-/-	-/-	-/-

Appendix III
Further accessories of the manufacturer GS corpuls

For further accessories please refer to Declarations of Conformity of

TD#	Product name
-/-	-/-