

Declaration of Conformity

GS Elektromedizinische Geräte G. Stemple GmbH

Hauswiesenstraße 26 86916 Kaufering

Germany

Product name

Arm corpuls cpr

Technical Documentation Reference Number

09100

DoC Version Number

001

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 *)
Annex VII combined with Annex V *)

Risk Class Im: Risk Class IIa:

Annex II without (4) *)

Risk Class IIb: Risk Class III: Annex II without (4) *)
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

2024-05-25

GS Elektromedizinische Geräte

G. Stemple GmbH

Kaufering (Germany), 2021-05-25

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
09100	Arm corpuls cpr	1.x	2b	61908	13-361	