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EC Declaration of Conformity for Medical Device

Document ID: CEGSS67HQMDE02 v01

Name and Address of the Manufacturer:	MAQUET GmbH Kehler Str. 31 D-76437 Rastatt

On our sole responsibility, we hereby declare that the product(s)

Product- / Trade Name:	Sterilizer
Description:	intended to sterilize medical items
Reference-No.:	GSS67H
Classification (acc. to Annex IX of MDD):	Class IIb

comply with the relevant provisions of the following Directive(s):

Directive 93/42/EEC on Medical Devices

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München Identification No.: 0123
Conformity Assessment Procedure:	acc. to Annex II excluding (4) of Directive 93/42/EEC
EC Certificate:	No. G1 028817 0045 Rev.01

Directive 2011/65/EU on the restriction of the use of certain substances in electrical and electronic equipment

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Directive 2014/68/EU on Pressure Equipment

Notified Body:	Kiwa Inspecta Sweden AB SE-10425 Stockholm Identification No.: 0409
Conformity Assessment Procedure:	acc. to Module B + C2 of Directive 2014/68/EU
EC type examination certificate:	19-1012642-100
Standards applied:	EN13445, EN14222, EN764-7
Modules for assessment of conformity of incorporated pressure bearing elements:	Vessel for sterilizer: Module B + F Pipework, heat exchangers: Article 4, section 3
Optional modules for assessment of conformity of incorporated pressure bearing elements:	Vessel for steam converter, vessel for steam generator: Module B + F Safety valves, level control: Module B + D

This declaration of conformity is valid from date of issue until 2024-05-08.

Rastatt, 2019-09-25

Holger Ullrich, Director Product Compliance SW
Signed on behalf of MAQUET GmbH