Sterisets
Medical Products

EU Declaration of Conformity

Manufacturer:	Sterisets International B.V. Ketelmeer 3 – 5347 JX Oss, The Netherlands Tel: +31 412 667 755 Email info@sterisets.com www.sterisets.com
Medical devices:	
Designation: Examination gloves	**Intended purpose:** To use in the medical field to protect patient and user for cross-contamination.
Risk Class:	According to Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Class I
Rule:	1 & 5
Conformity assessment route:	Annex IX
ISO 9001 certificate no. :	2156451
Certification company:	DEKRA Certification B.V.
Health and Safety requirements:	According to Annex II of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment. Category III
Notified Body:	SATRA Technology Europe Limited, number 2777, responsible for Module B and ongoing conformity (Module C2)
Harmonized standards:	EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016

We hereby declare that the above mentioned medical devices meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. This EU Declaration of Conformity is issued under sole responsibilityof Sterisets International B.V. and according to Annex IV of the referred Regulation. This DoC is valid for the products mentioned on the addendum.

Signature:	Jos van der Kwartel Digitally signed by Jos van der Kwartel Date: 2021.09.09 15:13:11 +02'00'
Name:	Jos van der Kwartel
Function:	Management representative
Place and Date:	Oss, September 2021

PART OF STI GROUP
Sti Sterisets International

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