

EU/EC Declaration of Conformity for CE Marking (CE mark)

Identification of the product: Sterile Gauze swabs

Date: 14/07/2020

Object of the declaration:

Reference	Product description	Nb of ply	Product size	Pcs/pouch	Pouches /box	Boxes/ carton
KZ181C220004 Ref CE SYLAMÉD : CGS050517	Sterile gauze swabs 5*5cm-8P folded edged	8	5 x 5 cm	2	25	60
KZ181C220005 Ref CE SYLAMÉD : CGS757517	Sterile gauze swabs 7.5*7.5cm- 8P folded edged	8	7,5 x 7,5 cm	2	25	48
KZ181C220006 Ref CE SYLAMÉD : CGS101017	Sterile gauze swabs 10*10cm- 8P folded edged	8	10 x 10 cm	2	25	36

Name and address of the manufacturer and/or his authorised representative:

Sylamed
3 Square de Maubeuge
75009 Paris - FRANCE

This declaration of conformity is issued under the sole responsibility of the manufacturer.

The object of the declaration described above is in conformity with the relevant

Community harmonisation legislation:

Directive 93/42/CEE - 14 June 1993

References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:

European Pharmacopoeia
NF EN ISO13485:2016, NF EN ISO 11135-1:2014

Classe: I Sterile classification according to annexe IX

This statement leans on the technical documentation established according to:
ANNEX V section 3 of the DIRECTIVE 93/42/EEC concerning Medical Devices, amended by
Directive 2007/47/CE delivered by :
Notified body LNE/G-MED 0459
Certificate n°20407 revision 6
Issued of the certificate: 30/08/2019
Expiration of the certificate: 16/05/2024

Sylvia LANDAU
Quality Manager

