

EU/EC Declaration of Conformity

Identification of the product: Non-sterile gauze swabs

Date: 22/06/2020

Object of the declaration:

Reference	Number of threads	Number of thicknesses	Folded dimensions	Box of	Boxes per carton
KZ181C120007	17	8	5 x 5 cm	100	100
KZ181C120008	17	8	7,5 x 7,5 cm	100	90
KZ181C120009	17	8	10 x 10 cm	100	60

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 ISO13485:2012

Classe : I NON STERILE classification according to annexe IX

This statement leans on the technical documentation established according to:

ANNEX VII of the DIRECTIVE 93/42/EEC concerning Medical Devices, amended by Directive 2007/47/CE

Déclaration to French Ministry (ANSM) :

Ref. 2015-DI-1643

Sylvia LANDAU
Quality Manager

