

EU/EC Declaration of Conformity

Identification of the product: Non sterile cotton crepe bandage

Date: 22/06/2020

Object of the declaration:

Reference	length	width	Box of	Boxes per carton
Z181B220001	5 m	6 cm	10	20
Z181B220002	5 m	8 cm	10	15
Z181B220003	5 m	10 cm	10	15

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):

Marquage CE certificat n°B.I-06728-97. Délivré le 08/12/1997 par le Ministère de la Santé

Sylvia LANDAU Quality Manager