

EU/EC Declaration of Conformity

Identification of the product: Elastic fixation bandage

Date: 22/06/2020

Object of the declaration:

Référence	Length	Width	Rolls/ box	Boxes/ carton
Z181B320001	4 m	4 cm	20	36
Z181B320002	4 m	6 cm	20	28
Z181B320003	4 m	8 cm	20	24
Z181B320004	4 m	10 cm	20	20

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

