

EU Declaration of Conformity to the
Medical Device Directive 93/42 EEC and amendments up to and including 2007/47/EC
For Skin Markers

P3

For the following P3 Range of Skin Markers:

<i>Product code</i>	<i>Description</i>
CSMK	Skin Markers (300 per case)
CSMK-CTN	Skin Markers (30 per carton)
CSMK-G	Skin Markers (300 per case)
UNSMK	Skin Markers (900 per case)

Which are labelled with the P3 logo and CE Mark

This is to certify that the class I sterile devices specified above conform to the above Directives as transposed in to national regulations and statutes of the United Kingdom, such compliance having been demonstrated via:


- A Technical File compliant to Annex VII
- Compliance to the Essential Requirements of Annex I
- Quality Assurance procedures in accordance with BS EN ISO13485:2016
- Compliance to Annex V Production Quality Assurance relating to sterility

The CE marking of product being subject to the achievement and maintenance of an Annex V certification by SGS Belgium NV, SGS House Noorderlaan 87 2030 Antwerp, Notified Body number 1639 and certificate number GB19/964727.

Authorised Representative.

Medical Device Management Limited
Block B, The Crescent Building,
Northwood,
Santry
Dublin 9,
D09 C6X8,
Ireland

This is to certify that the above statement is true and relates to product manufactured from this date.

Signed:	
Name: <i>Being a duly authorised officer of the Company</i>	Ian McEvoy
Date:	18/12/2020

P3 Medical Ltd, 1 Newbridge Close, Bristol, BS4 4AX, United Kingdom

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