

Mr. Dental Supplies BV

Mr.Dental
SUPPLIES

Declaration Of Conformity

Manufacturer: Mr. Dental Supplies BV
Julianastraat 114
6433 GE Hoensbroek
The Netherlands

Medical Device: See attachment 1 Part number(s) of CE Marked medical devices

GMDN code: 13735 Self sealing sterilisation pouches and sterilisation roll
35697 Micro applicator, bendable brush applicator
45007 Dental wedges

Classification MDD 93/42/EEC: Class I non-sterile, non-measurement
Rule 1: Self sealing sterilisation pouches and sterilisation roll
Rule 4: Dental wedge, Micro applicator, bendable brush applicator
Rule 5: Dental wedge, Micro applicator, bendable brush applicator

Mr. Dental Supplies BV hereby declares, under sole responsibility,

- that the above mentioned medical device meets the requirements of:
 - o EN ISO 13485:2012; Medical devices – Quality management systems – Requirements for regulatory purposes
 - o Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- that the above mentioned medical device is manufactured in conformity with the technical documentation and meet the requirements of the above mentioned Directive which apply to them
- that all documentation to support this declaration is available for review and shall be kept on file at Mr. Dental Supplies BV

Conformity assessment route: Annex II

Notified Body: Not applicable

CE Certificate number: Not applicable

Registration number Dutch CA:
NL-CA002-2017-42353: Sterilization packaging, single-use
NL-CA002-2017-42354: Dental restorative material applicator
NL-CA002-2017-42355: Dental wedge, single-use

Date CE marking affixed: 4 Aug 2017

Mr. Dental Supplies BV



Signed:

Hoensbroek, The Netherlands

A handwritten signature in blue ink, appearing to read "R. Kleijne", written over a horizontal line.

Mr. Ruud Kleijne
Regulatory & Quality Assurance

Date:

7 Jan 2018

Attachment 1: Part number(s) of the CE marked medical devices

Self sealing sterilization pouches

57x130 mm	455110
70x260 mm	455111
90x165 mm	455112
90x260mm	455113
135x260 mm	455114
135x350 mm	455115
190x280 mm	455116
250x350 mm	455117
300x430mm	455118

Steralisation roll

50mm - 200m	455210
75mm - 200m	455211
100mm - 200m	455212
150mm - 200m	455213
200mm - 200m	455214
250mm - 200m	455215
300mm - 200m	455216

Poly wedges

large - purple	211611
medium - yellow	211612
small - green	211613
extra small - blue	211614

Micro applicators

#1 super fine-white	201011
#2 fine-yellow	201012
#3 regular-blue	201013
#3 regular-green	201014
cylinder- black	201017
Mixed sizes, #1, #2, #3,	201021



Bendable Brush applicator

blue	201111
pink	201112
Brush applicator set	201131
Brush white	201132
Brush black	201133

Microtips

Set, 2 handles, 4x100 tips	201141
Handle 2 pcs	201143
tips green	201145
tips purple	201146
tips blue	201147
tips red	201148

Attachment 2: Used Harmonized Standards:

EN ISO 13485:2012	
EN ISO 14971:2012	
EN ISO 15223-1	
EN 1041:2008+A1:2013	
EN ISO 10993-1:2009	
EN ISO 10993-5:2009	
EN 1639:2009	
EN ISO 11140-1: 2009	
EN ISO 11607-1: 2009	
EN ISO 15223-1: 2016	