

DICHIARAZIONE DI CONFORMITA'

DIRETTIVA 93/42/EEC convertita in D.L. nr. 46 - 24/02/97 e successive modifiche

DECLARATION OF CONFORMITY

93/42/EEC DIRECTIVE converted in D.L. nr. 46 - 24/02/97 and subsequent amendments

PRODUTTORE (MANUFACTURER) MICERIUM S.p.A.
 VIA G. MARCONI, 83
 16036 AVEGNO (GE) – Italy
 TEL. +39-0185-7887870 FAX +39-0185-7887970
 E-mail quality@micerium.it

PRODOTTI (Products)

COD. PRODOTTO (Product ref.)	NOME COMMERCIALE (Proprietary name)	CLASSE (Class) (Annex IX)	REGOLA (Rule) (Annex IX)
EM35	ENA MATRIX 3,5mm 100pcs	1	5
EM35V3	ENA MATRIX 3,5mm 50pcs	1	5
EM45	ENA MATRIX 4,5mm 100 pcs	1	5
EM45V3	ENA MATRIX 4,5mm 50 pcs	1	5
EM55	ENA MATRIX 5,5mm 100pcs	1	5
EM55V3	ENA MATRIX 5,5mm 50 pcs	1	5
EM65	ENA MATRIX 6,5mm 100 pcs	1	5
EM65V3	ENA MATRIX 6,5mm 50pcs	1	5
EMAM	ENA MATRIX MOLAR BLACK RING	1	5
EMAP	ENA MATRIX PRE-MOLAR RED RING	1	5
EMAS	ENA MATRIX STEEL RING WITH WINGS "V" 1pc	1	5
EMC	ENA MATRIX KIT SECTIONAL MATRIX 35 MICRON	1	5
EMC35	ENA MATRIX SECTIONAL MATRIX 35 MICRON SMALL 50pcs	1	5
EMC45	ENA MATRIX SECTIONAL MATRIX 35 MICRON MEDIUM 50pcs	1	5
EMC55	ENA MATRIX SECTIONAL MATRIX 35 MICRON LARGE 50pcs	1	5
EMC65	ENA MATRIX SECTIONAL MATRIX 35 MICRON SUBGINGIVAL 50pcs	1	5
EMK1N	ENA MATRIX COMPLETE KIT	1	5
EMK1N-D	ENA MATRIX DEMO KIT	1	5
EMK3	TRIAL KIT ENA MATRIX without instruments	1	5
EMK3N	ENA MATRIX TRIAL KIT	1	5
EMK3N-C	ENA MATRIX COURSE KIT	1	5
EMKC	ENA MATRIX KIT SECTIONAL MATRIX 35 MICRON	1	5
EMKU	Ena Matrix Rubber Dam Kit	1	5
EMP1	ENA MATRIX TWEEZERS x MATRIX/WEDGE	1	5
EMP2	ENA MATRIX FORCEPS FOR RING	1	5

EMP4	ENA MATRIX FORCEPS FOR STEEL RING	1	5
EMP5	Ena Matrix Rubber Dam Frame 3 pcs	1	5
EMP5L	Ena Matrix Rubber dam Frame Large (12,7x12,7cm)	1	5
EMP5M	Ena Matrix Rubber dam Frame Medium (11,4x10,2)	1	5
EMP5S	Ena Matrix Rubber dam Frame Small (8,9x7,6cm)	1	5
EMP6	Ena Matrix Rubber Dam Punch	1	5
EMP7	ENA MATRIX FORCEPS FOR CLAMPS	1	5
EMRM53	ENA MATRIX METAL ROLL (h5mm-sp.0,035mm) 3m	1	5
EMRM55	ENA MATRIX METAL ROLL (h5mm-sp.0,050mm) 3m	1	5
EMRM63	ENA MATRIX METAL ROLL (h6mm-sp.0,035mm) 3m	1	5
EMRM65	ENA MATRIX METAL ROLL (h6mm-sp.0,050mm) 3m	1	5
EMRM73	ENA MATRIX METAL ROLL (h7mm-sp.0,035mm) 3m	1	5
EMRM75	ENA MATRIX METAL ROLL (h7mm-sp.0,050mm) 3m	1	5
EMRT08	ENA MATRIXTRANSPARENT ROLL (h8mm-sp.0,050mm)10m	1	5
EMRT10	ENA MATRIXTRANSPARENT ROLL (h10mm-sp.0,050mm)10m	1	5
EMT	ENA MATRIX DIASTEMA 15pcs 5 PCS x misure	1	5
EMT1	ENA MATRIX DIASTEMA 25pcs mesial superior	1	5
EMT2	ENA MATRIX DIASTEMA 25pcs distal superior	1	5
EMT3	ENA MATRIX DIASTEMA 25pcs inferior	1	5
EMU	Ena Matrix Rubber Dam Clamp Ki 5 pz.	1	5
EMU02	Ena Matrix Rubber Dam Clamp 22 for posterior	1	5
EMU22	Ena Matrix Rubber Dam Clamp 22 for posterior	1	5
EMU41	Ena Matrix Rubber Dam Clamp 41 for anterior	1	5
EMU51	Ena Matrix Rubber Dam Clamp 51 for anterior	1	5
EMU61	Ena Matrix Rubber Dam Clamp 61 for anterior	1	5
EMUD	Ena Matrix Rubber Dam	1	5
EMUD1	Ena Matrix Rubber Dam Light	1	5
EMUD2	Ena Matrix Rubber Dam Medium	1	5
EMUD3	Ena Matrix Rubber Dam Heavy	1	5
EMUD4	Ena Matrix Rubber Dam Roll	1	5
EMW GK	ENA MATRIX plastic wedge PROTECTIVE Assorted 40pcs	1	5
EMW GL	ENA MATRIX plastic wedge PROTECTIVE Large Violet 50pcs	1	5
EMW GM	ENA MATRIX plastic wedge PROTECTIVE Medium Pink 50pcs	1	5
EMW GS	ENA MATRIX plastic wedge PROTECTIVE Small White 50pcs	1	5
EMWL	ENA MATRIX plastic wedge Large Violet (purple) 100pcs	1	5
EMWM	ENA MATRIX plastic wedge Medium Pink 100pcs	1	5
EMWS	ENA MATRIX plastic wedge Small White 100pcs	1	5
EMWW	ENA MATRIX wooden wedge 400pcs 100 per size	1	5
EMWWL	ENA MATRIX wooden wedge large pink 100pcs	1	5

EMWWM	ENA MATRIX wooden wedge medium yellow 100pcs	1	5
EMWWS	ENA MATRIX wooden wedge small white 100pcs	1	5
EMWWXS	ENA MATRIX wooden wedge extra small orange 100pcs	1	5

FAMIGLIA (Family) : 1 SOTTOFAMIGLIA (SubFamily) : 1H Sistema di matrici per restauri (classe 1)

Matrix System for restorations (Class I)

DICHIARAZIONE:

DICHIARIAMO SOTTO LA NOSTRA ESCLUSIVA RESPONSABILITA' CHE I DISPOSITIVI MEDICI SOPRACITATI SONO CONFORMI ALLA DIRETTIVA DEL CONSIGLIO 93/42/EEC PER I DISPOSITIVI MEDICI E SUCCESSIVE MODIFICHE.
I DISPOSITIVI SONO CERTIFICATI IN ACCORDO ALL'ALLEGATO VII DELLA MEDESIMA DIRETTIVA.

DECLARATION:

WE HEREWITH DECLARE UNDER OUR SOLE RESPONSIBILITY THAT THE ABOVE MENTIONED MEDICAL DEVICES ARE CONFORMING TO THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES AND SUBSEQUENT AMENDEMENTS.
THE MEDICAL DEVICES ARE CERTIFIED ACCORDING TO ANNEX VII OF THE SAME DIRECTIVE AS BY CE CERTIFICATION.

Questo certificato non ha scadenza.

This certificate does not expire.

LUOGO, DATA DI RILASCIO (Place, date of issue): Avegno, 18/04/2018

FIRMA (Signature)

Amministratore Delegato (C.E.O.)
Eugenio Miceli

