

CE

0434

EC Declaration of Conformity

For the following equipment:

Non-Sterile Orthodontic Products and Accessories

Metal Bracket	Ceramic Bracket (with metal slot)	Metal Hook	Metal Stop
Buccal Tube	Elastic	Orthodontic Wire	Orthodontic Spring
Elastomeric Tie	Orthodontic Band		

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC) As Amended by 2007/47/EC with the compliance of conformity assessment **Annex II-exclusive section 4** to be certified by Det Norske Veritas (notify body number – 0434)

For the evaluation regarding the Class IIa product safety aspects, the following harmonized standards are applied:

ENISO 13485:2012 、 ENISO 14971:2012 、 EN 980:2008 、 EN 1041:2008 、 ENISO 10993-1:2009 、 ENISO 10993-5:2009 、 ENISO 10993-10:2010 、 EN ISO 10993-11:2009 、 EN 62366:2008 、 EN 1641:2009 、 ISO 15841:2014

The following EU - representative is responsible for the declaration:

Meimen Engineering Manufacturer AB

Astrakangatan 209,16552 Hasselby SWEDEN

Person responsible for making this declaration:

MEM Dental Technology Co., Ltd

2F., No.22 and 26, Ln.31, Sec.1, Huandong Rd., Xinshi Dist., Tainan City, Taiwan, R.O.C.

QA manager



2016.04.20

(Position/Title)

(Legal Signature)

(Date)