



Verification of Conformity

Applicant: Changzhou Ivorie Shengmei Packaging Technology CO., LTD
 Address: NO. 658, Qiyuexian Road, Xin'an, Hengshanqiao Town, Wujin District, Changzhou City, Jiangsu Province, China
 Product(s): Mouth Tray/Mouth Piece/Mouthpiece/Mouth Guard/Mouthguard
 Type(s): SG01/I-MT03B/I-MT01B/I-MT02C/I-ASTB02/YYDE004/YYDE005/YYDS006/YYSY001/YYDE001/YYDE003/YYDS005/YYDS004/YYDY004/YYDY005/YYDY006/YYDE002/I-MT04/NV02/NV01/TI01/NV03/NV04/I-TWL-LT
 Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Medical Device Directive (93/42/EEC).

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

Standard(s): EN ISO 14971:2012; EN ISO 15223-1:2016;
 EN 1041:2008+A1:2013; EN ISO 10993-12:2009/AC:2010;
 EN ISO 10993-5:2009; EN ISO 10993-10:2013

The review result of the technical files and test report support the self declaration for the devices listed above. Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

SUNGO Cert GmbH

