

File No: CE-TCF-001



EC Declaration of Conformity



Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Applicant

Name: HENGSHUI XINGMAI IMP.&EXP.CO.LTD

Address: No.7, ZHENHUA, NEW ROAD, DEVELOPMENT DISTRICT, HENGSHUI CITY, CHINA

Product

Name: Posture Corrector, Lumbar Support, Knee Brace, Shoulder Brace, Neck Brace, Wrist Brace, Ankle Brace, Elbow Brace, Arm Sling, Neck Hammock

Type: See annex

Classification: Class I

Rule: According to Rule 1

We confirm our product can meet the requirement of Medical Device Directive and the following standards.

EN ISO 13485:2013
EN ISO 13485:2013
EN 1041:2008+A1:2013
EN ISO 10993-12:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013

Signature:

Date:



2018. 6

Annex

No.	Product Name	Type
1	Posture Corrector	XM-F3, XM-F4, XM-F5, XM-F6, XM-F7.M,L
2	Lumbar Support	S,M,L
3	Knee Brace	S,M,L,XL,XXL
4	Shoulder Brace	One size
5	Neck Brace	XM-XB2,One size of all
6	Wrist Brace	XM-4 One size of all
7	Ankle Brace	One size fit all
8	Elbow Brace	One size fit all
9	Arm Sling	One size fit all
10	Neck Hammock	One size fit all

