

Technical Construction File: TCF-001 (ver.1.0)

DECLARATION OF CONFORMITY

We, SKMMEDICAL CO., LTD.

5th Floor, 1640, Sangam-dong, Mapo-gu, Seoul, KOREA 03911

declare under our sole responsibility that the product

Product : OSIS Soft Brace
Type designation : OSW-01A,OSW-02A,OSW-03A,OSW-04A,OSK-01A,OSK-02A,OSK-03A
OSK-04A, OSR-01A,OSR-02A,OSA-02A
Ratings : Cotton, Polyurethan, Neoprene, Span, Nylon, Polyester, Rubber, Stretch nylon.
Serial Number: none
Year of manufacture : 2017

to which this declaration relates is in conformity with the following standard(s) or other normative document(s);

EN ISO12100-1 (2003)	Safety of machinery - Basic concepts, general principles for design, Part 1 : Basic terminology, methodology
EN ISO12100-2 (2003)	Safety of machinery - Basic concepts, general principles for design, Part 1 : Technical principles
EN ISO10218-1 (2006)	Manipulation Industrial Robots - Safety
EN60204-1 (2008)	Safety of machinery - Electrical equipment of machines Part 1 : General requirements
EN61000-6-2 (2005)	Electromagnetic compatibility (EMC), Part 6-2: Generic standards - Immunity for industrial environments
EN61000-6-4 (2007)	Electromagnetic compatibility (EMC), Part 6-4: Generic standards - Emission for industrial environments

following the provisions of Directive(s);

2006/42/EC	Directive on the approximation of the laws of Member States relating to machinery
2006/95/EC	Directive on the laws of Member States relating to electrical equipment designed for use with certain voltage limits (OJ L374 27.12.2006)
2004/108/EEC	Council Directive on the approximation of laws of the Member States relating to electromagnetic compatibility

Seoul 03911 R.O.K / 14.08.2017

Shin Kyeong Kai

