

EU DECLARATION OF CONFORMITY (No. 2016/699-01)

This Declaration of Conformity is issued under the sole responsibility of the manufacturer

MANUFACTURER

Company name	Skel-Ex B.V.
Full address	Molengraaffsingel 12
Postal code	2629 JD
Place	Delft
Country	The Netherlands

IDENTIFICATION MEDICAL DEVICE

(Commercial) name	Skel-Ex One
Function/intended use	Arm Support
Model	Mark 0
Risk Class	I

The object of the Declaration described above is in conformity with all relevant provisions of

Medical Devices Directive 93/42/EEC

In conjunction with the following relevant harmonised standard or technical specification

EN ISO 14971:2012

Signed for and on behalf of

Place of issue: Delft
The Netherlands

Identity:
Function:

Mr. G. Genani
Director

Date of issue: April 25, 2017

Signature

