DECLARATION OF CONFORMITIY

Declaration of conformity

In compliance with the Council Directive 93/42/EEC Annex II
of 14. June. 1993 / Changed 05. Sep. 2007, concerning medical devices,
the company

ORMED GmbH
Merzhauser Straße 112
D-791 00 Freiburg

declares under its sole responsibility as manufacturer of these products, that the products of the product line

ARTROMOT® (see Annex)

fulfill the essential requirements of Annex I of the Council Directive 93/42/EEC.

With reference to Rule 9 of the Council Directive 93/42/EEC/Annex 9, the devices of the product line are classified as: **risk class IIa**

CE 0297

Notified Body:
DQS Medizinprodukte GmbH
August-Schanz-Straße 21
60433 Frankfurt am Main

Freiburg, February 10th, 2017

- QA Management Representative, Bernhard Krohne-

This certificate is valid until expiry of the certificate referred to.
(the certificate can be downloaded from: https://de.dqs-ul.com/kunden/kundendatenbank.html)

Annex:

Product Family	Versions:
ARTROMOT®-K1	*ARTROMOT®-K1 Classic* *ARTROMOT®-K1 Standard* *ARTROMOT®-K1 Standard Chip* *ARTROMOT®-K1 Comfort* *ARTROMOT®-K1 Comfort Chip*
ARTROMOT® ACTIVE-K	*ARTROMOT® ACTIVE-K* *Chattanooga™ ACTIVE-K*
ARTROMOT®-S3	*ARTROMOT®-S3 Standard* *ARTROMOT®-S3 Comfort*
ARTROMOT®-S4	*ARTROMOT®-S4 Comfort*
ARTROMOT®-SP3	*ARTROMOT®-SP3 Standard* *ARTROMOT®-SP3 Standard Chip* *ARTROMOT®-SP3 Comfort* *ARTROMOT®-SP3 Comfort Chip*
ARTROMOT®-E2	*ARTROMOT®-E2* *ARTROMOT®-E2 Compact*