EC-CERTIFICATE
(Full quality assurance system)

DQS Medizinprodukte GmbH

hereby certifies that the company

Ormed GmbH

Merzhauser Straße 112
79100 Freiburg
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

An audit, documented in a report, performed by DQS, has verified that this quality assurance system fulfils the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Devices for passive joint mobilization / Continuous Passive Motion CPM according annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. In case of class Is devices the certificate is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. In case of class Im devices the certificate is restricted to the aspects of manufacture concerned with the conformity of the products with metrological requirements.

Certificate registration No.	020812 MR2
Certificate unique ID	170520289
Effective date	2011-08-18
Expiry date	2016-08-17
Frankfurt am Main	2011-08-18

Frank Graichen
Managing Director

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Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Notified Body Number 0297.

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Annex to Certificate
Certificate registration No.: 020812 MR2
Certificate unique ID: 170520289
Effective date: 2011-08-18

Ormed GmbH

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Device family	Products	UMDNS-Code	Class
Rehabilitation devices and active protheses	ARTROMOT® K1	17-138	IIa
	ARTROMOT® K2	17-138	IIa
	ARTROMOT® K3	17-138	IIa
	ARTROMOT® K4	17-138	IIa
	ARTROMOT® SP2	17-138	IIa
	ARTROMOT® SP3	17-138	IIa
	ARTROMOT® S2 PRO	17-138	IIa
	ARTROMOT® S3	17-138	IIa
	ARTROMOT® E2	17-138	IIa
	ARTROMOT® ACTIVE-K	17-138	IIa