EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Ormed GmbH

Bötzinger Straße 90
79111 Freiburg
Germany

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

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills 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 (CPM-Therapy / Continuous Passive Motion) and Devices for active joint mobilization (CAM-Therapy / Controlled Active Motion) according annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification 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. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	020812 MR2
Certificate unique ID	170771100
Effective date	2020-08-07
Expiry date	2024-05-26
Frankfurt am Main	2020-08-07

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 020812 MR2
Certificate unique ID: 170771100
Effective date: 2020-08-07

Ormed GmbH

Bötzinger Straße 90
79111 Freiburg
Germany

Device family	Products	UMDNS-Code	Class
Rehabilitation devices	ARTROMOT®-K1	17-138	IIa
	ARTROMOT®-SP3	17-138	IIa
	ARTROMOT®-S3	17-139	IIa
	ARTROMOT®-E2	17-139	IIa
	ARTROMOT® ACTIVE-K	15-220	IIa
	ARTROMOT®-S4	17-139	IIa