Certificate

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the undermentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2016.

Through an audit performed on behalf of

Fuhrmann GmbH

Gewerbegebiet Bövingen 139, 53804 Much, Germany

it could be demonstrated that a quality management system

according to

DIN EN ISO 13485:2016

"Medical devices – Quality management systems – Requirements for regulatory purposes"

for the

manufacture and distribution of sterile and non-sterile medical devices: wound care products, surgical sets, instruments, devices and kits for the hospital ward and medical practice

has been established and implemented.

This certificate is only valid under the conditions stated in the audit report mentioned hereafter. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number

Registered under

Valid until

010-18-1212

Z19/04415E

February 13th, 2022

Valid as of: February 14th, 2019

Certification Body



Annex I to Certificate Z/19/04415E

Number of Pages: 1 von 1



The scope of this certificate includes the following production site:

Fuhrmann Medical s.r.o. Komenskeho 404 35709 Harbatov Tschechische Republik