

## **Certificate of Approval**

This is to certify that the Management System of:

## MEDIN, a.s.

Vlachovická 619, 592 31 Nové Město na Moravě, Czech Republic

has been approved by LRQA to the following standards:

ISO 13485:2016



P.G. Cornelissen - Area Manager North Europe Issued By: Lloyd's Register EMEA for and on behalf of: Lloyd's Register Quality Assurance Limited

Current Issue Date: 12 June 2018 Expiry Date: 11 June 2020 Certificate Issue Number: 10111987 Original Approvals: ISO 13485 – 12 June 2018



Approval Certificate Number: ISO 13485 - 00013114

The scope of this approval is applicable to:

Design, development, production, purchase, servicing and sale of medical devices for surgery, orthopedics, traumatology and sterile medical devices for dentistry.





Lloyd's Register Group Limited, its affiliates and subsidiaries, including Lloyd's Register Quality Assurance Limited (LRQA), and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'Lloyd's Register'. Lloyd's Register assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document no howsoever provided, unless that person has signed a contract with the relevant Lloyd's Register entity for the provision of this information or advice and in that case any responsibility on liability is exclusively on the terms and conditions set on the torntract. Issued By: Lloyd's Register EMEA, Táborská 31, 140 00 Prague 4, Czech Republic for and on behalf of: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom



Lloyd's Register EMEA Táborská 31 140 00 Praha 4 Česká republika

www.lr.org/cz

30 April 2020

MEDIN a.s.

**<u>Re</u>**: To confirm that the certificate validity has been extended for a period of up to six months from the expiry date.

To whom it may concern

I am writing regarding your request for the certificate renewal assessment to be postponed, based on IAF ID3: 2011 Management of Extraordinary Events or Circumstances Affecting ABs, CBs, and Certified Organizations).

Based on the information available from your organization's management system, we have determined that your management system certification validity can be extended for a maximum of six months.

However, as soon as the effects of Covid-19 have subsided, it will be necessary to undertake a certificate renewal assessment as soon as possible. If the recertification is successfully completed during the six-month extension period, an updated certificate will be issued.

The date of issuance of the new certificate will be the date of completion of our technical review, which will be conducted after the completion of the renewal assessment. The expiry date will be three years from the expiry date of the current certificate.

It should be noted that IAF ID3 requirements are that if the renewal assessment (including technical review) is not completed during the extension validity period of 6 months, the certificate will be suspended, and an assessment based on the initial assessment duration will be required to reinstate the certificate.

Organisation name: MEDIN, a.s. Address: Vlachovická 619, 592 31 Nové Město na Moravě, Czech Republic Client No.: PRA00000201

Assessment standard: ISO 13485:2016

scope of approval: Design, development, production, purchase, servicing and sale of medical devices for surgery, orthopedics, traumatology and sterile medical devices for dentistry.

Certificate identification No.: 10111987 Expire date of current certificate: 11 June 2020 End of extension validity period:11 December 2020

Paul Graaf

Area Operations Manager North Europe Lloyd's Register AMEA, Prague office for and on behalf of: Lloyd's Register Quality Assurance Limited