

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.



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30 April 2020

MEDIN a.s.

Re: 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