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CMI MEDICAL

CENTER FOR
CERTIFICATION
OF MEDICAL DEVICES

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**Are you seeking conformity assessment for your
medical device and looking for a suitable partner ?**

Meet the Czech Metrology Institute!



We are a newly appointed Notified Body 1383 for conformity assessment of Medical Devices in accordance with MDR. We offer high-quality services thanks to our broad team of highly educated and experienced professionals.

Do you want to familiarize yourself with all the MDR requirements that are placed on you?

Visit our website where you will find:

- the relation of the new regulation MDR and the old directive MDD
- an overview of the new MDR requirements for manufacturers
- an overview of the requirements for the use of the extended transition period
- a step-by-step guide for implementing MDR requirements into your system
- other useful methodological guides for conformity assessment, classification etc.

How to prepare for conformity assessment at CMI?

First, you need to prepare **documentation** of adequate quality to meet all the requirements of the MDR.

Then, send us a **non-binding inquiry** by filling out the form that is available for download on our website. We will review it and if we are able to assess the conformity of the medical device, we will send you a **non-binding offer** with an **estimated price**.

If you are satisfied with the offer, proceed by filing the **official request for conformity assessment** and providing all required attachments. In case of its successful review, we will then proceed with signing a **framework contract** and setting a deadline for you to submit complete **technical documentation**.

After the submission, we will conduct a complex review of your documentation, select professionals suitable for the assessment of your Medical Device, sign the **implementation agreement** with a specified price estimate, and **begin the assessment process**.

In case of successful completion of the assessment process, we will issue you a **certificate** and you can then launch your medical device on the market.

A detailed description of the entire process can be found on our website at www.cmi.gov.cz/mdr.

What range of services can we offer?

We are authorized to assess Medical Devices of risk class **Is, Ir, Im, IIa and IIb** for **20 basic and 18 horizontal codes**.

A complete list of our scope, including limitations, can be found on our website at www.cmi.gov.cz/mdr.

And how much is it going to cost?

The cost for conformity assessment always depends on the specific medical device, its complexity, risk class and the complexity of the manufacturing process.

The individual rates for conformity assessment services are transparently published in the price list on our web-site: www.cmi.gov.cz/mdr. We have set these rates as **one of the lowest in the EU** while also taking into account the size of the company.

We will be happy to prepare a specific offer for your medical device based on a non-binding inquiry.

CMI MEDICAL

YOUR PARTNER IN MEDICAL DEVICE
CONFORMITY ASSESSMENT

Contact us

Do you require assistance or wish to verify if your medical device qualifies for assessment by CMI?
Do not hesitate to reach out to us:

Czech Metrology Institute

Medical Devices Certification Center
Hvoždanská 2053/3
148 00 Praha-Chodov

medical@cmi.gov.cz
www.cmi.gov.cz/visitus

Contact person:

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