



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2020-MDD/QS-121

issued in compliance with the Council Directive 93/42/EEC as amended,  
certifies that the medical device of Class IIa,

**Healthcare Software MWPharm**  
**Models: MwPharm 4.0, MwPharm++, MwPharmOnline, MwPharmASIA**

manufactured by company

**MEDIWARE a.s.**  
Evropská 655/116, Dejvice, 160 00 Praha 6, Czech Republic

**is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended.**

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT-106 and the Final protocol No. 310486/2020.

*This certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if such is required. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26<sup>th</sup>, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.



Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on December 22<sup>nd</sup>, 2020



Certificate history:

<b>Revision</b>	<b>Date of issue</b>	<b>Application for Conformity Assessment of MD number</b>	<b>Description</b>
<b>0</b>	<b>December 22<sup>nd</sup>, 2020</b>	<b>31048631/2020</b>	<b>First issue</b>