# DECLARATION of CONFORMITY

**MEDITECH Kft.**
(H-1184 Budapest, Mikszáth Kálmán u. 24, Hungary),
as manufacturer of the **Meditech ABPM-06 (BP6)**
Ambulatory Blood Pressure Monitors,
hereby states that the country of origin of the devices is Hungary and they meet all requirements of **93/42/EEC Medical Device Directive** (with the existing Amendments), especially the essential requirements (Annex I) and the requirements of the product-relevant standards regarding the Electrical Safety, Electromagnetic Compatibility and the relevant Particular and Collateral Standards such as:

**EN 60601-1:2006 + AC:2010 + A1:2013; EN 60601-1-2:2015;**
**EN 60601-1-11:2015; EN 80601-2-30:2010**
**EN 80601-2-30:2010/A1:2015; EN 62304:2006**
**EN 60601-1-6:2010; EN 62366:2008**
**EN ISO 14971:2012**

Serial No.:

The products are classified to **Risk Class IIa**
according to Annex IX, rule 10 of the Medical Device Directive.

The quality management system conforms to the Full quality assurance management (Annex II.) requirements of the Medical Device Directive.

According to the certificates issued by the Notified Body
**CE Certiso Ltd.**
(H-2092 Budakeszi, Erdő u. 101., Hungary)
the devices are entitled to bear the **„CE 2409"** mark.

Date:

25-05-2021

***István Szőllősi M.D.***
managing director