DECLARATION of CONFORMITY

MEDITECH Kft.
(H-1184 Budapest, Mikszáth Kálmán u. 24, Hungary),
as manufacturer of the **Meditech ABPM-05** (**BP5**)
Ambulatory Blood Pressure Monitor,
hereby states that the country of origin of the device is Hungary and it meets 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 product is 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