CE

otiom®

EC Declaration of Conformity

Company name:	Otiom A/S
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Postcode:	9220
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Country:	Denmark
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E-mail:	info@otiom.com

We herewith declare that the Otiom System, consisting of

Product description:	Tracking device
Product name:	Otiom Tag
Part Number:	30100001
Since year of manufacture:	2020
and	
Product description:	Bluetooth Beacon
Product name:	Otiom Home Base
Part Number:	30100006
Since year of manufacture:	2020
and	
Product description:	Smartphone App
Product name:	Otiom App
Part Number:	V1.x
Since year of manufacture:	2020

meets the provisions of the council directive 93/42/EEC + 2007/47/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.
It is classified as Class I, according to rule 12 of Annex IX of the directive, and conformity is declared according to Annex VII.

Additionally, conformity is declared with the following European directives:
2014/53/EU (RED)
2011/65/EU (RoHS)

and harmonized European standards, which applies to the product:
ETSI EN 300 328 V2.1.1: 2016 (Wideband transmission systems)
EN62368-1: 2014/AC:2017 (Safety of IT equipment)
Draft ETSI EN 301 489-1 V2.2.0: 2017 (EMC)
Draft ETSI EN 301 489-17 V3.2.0: 2017 (EMC)
EN 62479: 2010 (EMF)
EN 60950-1: 2006+A11: 2009+A1: 2010+A12: 2011+A2: 2013 (Safety of IT equipment)

Aalborg 2020-01-30:

Thomas Pedersen, CEO