AND

Declaration of Conformity

The manufacturer, A&D Company, Limited, is exclusively responsible for the declaration of conformity.

Manufacturer 's Name and Address:
A&D Company, Limited
1-243 Asahi, Kitamoto-shi, Saitama-ken. 364-8585 Japan
European Representative:
A&D INSTRUMENTS LIMITED
Unit24/26 Blacklands Way
Abingdon Business Park
Abingdon, Oxon
OX14 1DY United Kingdom
Product Category:
Blood pressure monitor
Model Number:
<u>UM-211</u>
Classification/Rule:
II a/ Rule10
✓ The product complies with the requirements of the Directive
93/42/EEC Annex I and the certified quality system according
to Annex II excluding (4).
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Standards: EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010,
EN 60001-1:2000/A1:2013, EN 60001-1-2:2013, EN 60001-1-6:2010, EN 62304:2006, EN 62366:2008,
EN ISO 15223-1:2016, EN 1041:2008, EN ISO 10993-1:2009,
EN ISO 14971:2012, IEC 80601-2-30:2009/A1:2013, ISO 81060-2:2013
Notified Body:
TÜV SÜD Product Service GmbH (0123)
Ridlerstraße 65 80339 MÜNCHEN, GERMANY
Certificate number: G1 085349 0008 Rev. 00
This declaration is valid until the expiration date of the MDD annex II
certificate by TÜV SÜD Product Service GmbH.
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✓ The product complies with the requirements of the Directive
• •
2011/65/EU.
Notified Body: Not Applied
Place and date: Saitama, Japan, 14 Mar. 2019
File number: <u>19031404</u>
Mento
Minoru Saitou
Chief of Quality Control Office
A&D Company, Limited