# Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

## MANUFACTURER

<table>
<thead>
<tr>
<th>Name of Company</th>
<th>Address</th>
<th>SRN</th>
</tr>
</thead>
<tbody>
<tr>
<td>ActiGraph, LLC</td>
<td>49 E. Chase Street Pensacola, Florida 32502 United States of America</td>
<td>Not currently applicable</td>
</tr>
</tbody>
</table>

## AUTHORIZED REPRESENTATIVE

<table>
<thead>
<tr>
<th>Name of Company</th>
<th>Address</th>
<th>SRN</th>
<th>Telephone/fax/email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergo Europe</td>
<td>Prinsessegracht 20 2514 AP The Hague The Netherlands</td>
<td>Not currently applicable</td>
<td>+31.70.345.8570 - phone +31.70.346.7299 - fax <a href="mailto:EmergoEurope@ul.com">EmergoEurope@ul.com</a></td>
</tr>
</tbody>
</table>

## PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Product Code / Catalog Number</th>
<th>Basic UDI-DI</th>
</tr>
</thead>
<tbody>
<tr>
<td>ActiGraph</td>
<td>wGT3X-BT</td>
<td>0853048008008UP</td>
</tr>
</tbody>
</table>

**Intended Purpose**

The ActiGraph activity monitors are small wrist-worn monitors designed for documenting physical movement associated with applications in physiological monitoring. The devices are intended to monitor the activity associated with movement during sleep. The ActiGraph activity monitors can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

## RISK CLASS FOR MEDICAL DEVICES

<table>
<thead>
<tr>
<th>Device Classification</th>
<th>Common Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rule: 12 (Annex IX, III. Classification, Page 55)</td>
<td></td>
</tr>
</tbody>
</table>
ActiGraph declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Device Regulation (MDR) 2017/745

COMPANY REPRESENTATIVE: Adam Simon

TITLE: Regulatory Affairs Manager

SIGNATURE: Adam T Simon

PLACE: United States of America

DATE: 2020-08-03
wGT3X-BT Declaration of Conformity (2020-08-03)

Final Audit Report

Created: 2020-08-03
By: Adam Simon (adam.simon@actigraphcorp.com)
Status: Signed
Transaction ID: CBJCHBCAABAAhRbNQ4XyqtsG2wThJaEiS6wwlWLArI-CF

"wGT3X-BT Declaration of Conformity (2020-08-03)" History

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2020-08-03 - 9:03:17 PM GMT- IP address: 104.137.108.54

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2020-08-03 - 9:03:57 PM GMT

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