

## EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

### MDR 747381 R000

**Manufacturer:** Itamar Medical Ltd.

**Address:**

9 Halamish Street,  
PO 3579  
Caesarea  
3088900  
Israel

**Single Registration Number:** IL-MF-000012046

**EU Authorised Representative:** Arazy Group GmbH

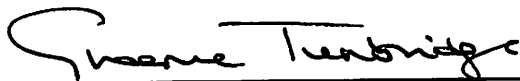
**Address:**

The Squire 12  
Am Flughafen  
60549 Frankfurt am Main  
Germany

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-07-13**

Current Issue Date: **2024-02-15**

Starting Validity Date: **2024-02-15**

Expiry Date: **2027-07-12**

...making excellence a habit.™



## EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

### MDR 747381 R000

#### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Watch-PAT300	Class IIa
uPAT Probe	Class IIa
zzzPAT / WPInterface software	Class IIa
RESBP sensor	Class IIa
WatchPAT ONE / WatchPAT ONE E	Class IIa
WatchPAT ONE mobile application	Class IIa

First Issue Date: **2022-07-13**

Current Issue Date: **2024-02-15**

Starting Validity Date: **2024-02-15**

Expiry Date: **2027-07-12**

...making excellence a habit.™

Page 2 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.



## EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

### MDR 747381 R000

#### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
2022-07-13	3412646	Issued
Current	30108924	Supplemented – addition of WatchPAT ONE / WatchPAT ONE E and WatchPAT ONE mobile application devices.

First Issue Date: **2022-07-13**

Current Issue Date: **2024-02-15**

Starting Validity Date: **2024-02-15**

Expiry Date: **2027-07-12**

...making excellence a habit.™

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.