

<b>Manufacturer</b>	<b>Authorized European Representative</b>	<b>Notified Body</b>
Covidien Inc 15 Hampshire Street Mansfield, MA 02048 USA (formerly: Nellcor Puritan Bennett L.L.C., a division of Tyco Healthcare Group LP)	Covidien Ireland Limited IDA Business & Technology Park Tullamore, Ireland	TÜV SÜD Product Services GmbH Ridlerstrasse 65 D-80339 Munich Germany 0123

## Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and/or<sup>1</sup>
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Covidien LLC
Manufacturer address and contact details	15 Hampshire St. Mansfield, MA 02048 USA Contact: rs.eudamedinquiries@medtronic.com
Single Registration Number (SRN) (if available)	US-MF-000028763

Authorised Representative name (if applicable)	Covidien Ireland Limited
Authorised Representative address and contact details	IDA Business and Technology Park Tullamore, Co. Offaly R35 H903 Ireland
Single Registration Number (SRN) (if available)	IE-AR-000002274

Notified body name (if applicable)	TUV SUD Product Services GmbH
Notified body number (if applicable)	

<sup>1</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

	0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 077790 0060
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 May 2024
End date of extended validity/transition period	31 December 2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*<sup>2</sup>
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

Expired *before* 20 March 2023:

- Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
- A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intend to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Expired/expires *after* 20 March 2023:

<sup>2</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body



## Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s) (if applicable)
10005002	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10019217	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10020263	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10020264	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
110020265	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10020269	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10020407	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10020409	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10020410	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10020414	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10020419	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10035864	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10035873	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10035874	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10035880	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10043551	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	







































































































































304/13607	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
304/13614	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
304/13874	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
304/6648	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
304P13358Z	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
304P14234	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
305P8856	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
305R8955	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
305R8956	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
305R9941	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
306P8193	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
309/6539	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
309R14254	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
331D5656	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
331U5661	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
332U5115	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
332U5663	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
350/5807	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
350/5957	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
350U19006	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
350U5865	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
350U5879	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
351P5856	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	







8805	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
8806	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
8807	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
8808	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
8809	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
8810	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
8811	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5CN70ED	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5CN70ER	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5CN70ES	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
6CN75ED	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
980HFO2T-MFG	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
6CN75ER	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
6CN75ES	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
7CN80ED	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
FPD2126A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
FPD2126A-IN	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
G-060526-00	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
KIT3420A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
MXL70A-GR-DS	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
MXL70A-WH-BR	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
MXL70A-WH-FR	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
MXL70A-WH-PL	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	



8CN85ER	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
8CN85ES	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
9CN90ED	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
9CN90ER	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
9CN90ES	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
BAT3271A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	