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Document Title:	Addendum to EC Declarations of Conformity to Council Directive 93/42/EEC	
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## Addendum to Declaration of Conformity

Covidien llc declares that the Medical Device(s) specified in Appendix A comply with Article 120 of the Regulation (EU) 2017/745 (MDR) as amended by Regulation (EU) 2023/607 and 93/42/EEC (MDD).

This addendum to the Declaration(s) of Conformity is supported by the EC Certificate according to the provisions of the relevant Annex(es) of 93/42/EEC (MDD), and the evidence of compliance to the conditions presented under Article 1 Paragraph 3c of the amended Regulation (EU) 2023/607.

The Medical Device(s) specified in Appendix A:

- Continue to comply with 93/42/EEC (MDD);
- Do not have any significant changes in design or intended purpose since 26 May 2021; and
- Do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health
- Covidien has a quality management system compliant with Article 10(9) of Regulation (EU) 2017/745 (MDR).
- Covidien has submitted a formal application in accordance with Section 4.3, first subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment and a signed agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) before the expiry date of the listed certificate for the Medical Device(s) specified under Appendix A.
- Post market surveillance, market surveillance, vigilance, registration of economic operators and of devices in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device (s) listed Medical Device(s) specified under Appendix A.

### Signature, Date of Issue:

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Date: February 23, 2024

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## Addendum to Declaration of Conformity

Covidien llc declares that the Medical Device(s) specified in Appendix A comply with Article 120 of the Regulation (EU) 2017/745 (MDR) as amended by Regulation (EU) 2023/607 and 93/42/EEC (MDD).

This addendum to the Declaration(s) of Conformity is supported by the EC Certificate according to the provisions of the relevant Annex(es) of 93/42/EEC (MDD), and the evidence of compliance to the conditions presented under Article 1 Paragraph 3c of the amended Regulation (EU) 2023/607.

The Medical Device(s) specified in Appendix A:

- Continue to comply with 93/42/EEC (MDD);
- Do not have any significant changes in design or intended purpose since 26 May 2021; and
- Do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health
- Covidien has a quality management system compliant with Article 10(9) of Regulation (EU) 2017/745 (MDR).
- Covidien has submitted a formal application in accordance with Section 4.3, first subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment and a signed agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) before the expiry date of the listed certificate for the Medical Device(s) specified under Appendix A.
- Post market surveillance, market surveillance, vigilance, registration of economic operators and of devices in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device (s) listed Medical Device(s) specified under Appendix A.

### Signature, Date of Issue:

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