ARTICLE 120 SELF-DECLARATION

EU MDD DECLARATION OF CONFORMITY GLOBAL ADDENDUM

FOR EXTENDED TRANSITION TO MDR

Legal Manufacturer (LM)	Name: Z-Medica, LLC Address: 4 Fairfield Boulevard Wallingford Connecticut 06492 USA Contact: Kelsey Moylan Sr. Regulatory Affairs Manager, Product Management kelsey.moylan@teleflex.com +1 (919) 820-0449 SRN: US-MF-000029799
Authorized Representative	Name: Teleflex Medical Address: IDA Business and Technology Park Dublin Road Athlone Co. Westmeath Ireland Contact: Ida Foley Director of Regulatory Affairs – EMEA ida.foley@teleflex.com +353 (0)87 751 9577 SRN: IE-AR-000015869
Incoming Notified Body (MDR NB)	Name: BSI Group the Netherlands B.V. Identification Number: NB 2797
Notified Body That Issued the Certificate Under MDD (MDD NB)	Name: BSI Group the Netherlands B.V. Identification Number: NB 2797

Z-Medica, LLC declares that the product(s) listed in Appendix A meet the provisions of Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 (MDR) as regards the transitional provisions for certain medical devices.

This declaration is made on the basis that the product(s) listed in Appendix A are currently compliant to:

☒ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), the provisions of 120(3c), and are intended to or have been confirmed to meet the provisions of Regulation (EU) 2017/745 (MDR).

☐ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), the provisions of Article 120(3c), Article 120(2) points (a) or (b) of MDR, and are intended to meet the provisions of Regulation (EU) 2017/745 (MDR).

☐ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), and Article 120(3c) of MDR.

Furthermore, Z-Medica, LLC declares:

☒ A formal application has been lodged in accordance with Section 4.3, first subparagraph, of Annex VII MDR before MDD certificate expiration or before 26 May 2024. The LM and MDR NB have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII MDR before 26 September 2024.

☐ A Quality Management System (QMS) will be implemented in compliance with Article 10(9) of Regulation (EU) 2017/745 (MDR) prior to 26 May 2024.

☐ A Quality Management System (QMS) has been implemented in compliance with Article 10(9) of Regulation (EU) 2017/745 (MDR), but is not yet certified.

☒ A Quality Management System (QMS) has been certified in compliance with Article 10(9) of Regulation (EU) 2017/745 (MDR).

☒ Post-market surveillance, market surveillance, vigilance, and economic operator requirements will be conducted pursuant to Article 120(3e) of the Regulation (EU) 2017/745 (MDR).

☒ The extended transitional period for the product(s) listed in Appendix A shall end on the dates stated in Appendix A, as set forth in Article 120(3) of the MDR.

☒ The product(s) listed in Appendix A will continue to comply with Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD); will not undergo any significant changes to the design or intended purpose; and do not present and unacceptable risk to health or safety of patients, users, or other persons or to other aspects of the protection of public health.

Approvals:

Company Name:	Z-Medica, LLC
Name, Title, and Email Address of Approver:	Kelsey Moylan Sr. Regulatory Affairs Manager, Product Management kelsey.moylan@teleflex.com
Signature of Approver:	
Date Approved:	11-Apr-2024
Place of Issue:	Morrisville, NC

Change History for Declaration of Conformity Addendum:

Revision	Date	Reason for Revision
00	08-Mar-2024	Initial release of EU MDD Declaration of Conformity Global Addendum
01	11-Apr-2024	Added additional quotation to ensure reference to Technical Documentation review quote is captured (Q661787). Revised LM address format to align with BSI certificates.

APPENDIX A

Product Name	Product Code(s)	MDD EC Certificate(s) No	MDD EC Certificate(s) Expiry Date	End date for Extended Transition Period	MDR Product Class	MDR Class Rule	MDR Conformity Assessment Route(s)	Substitute Devices (if applicable)	Scheduled MDR Submission Date	Device Schedule and/or Approved Quote Reference
QuikClot™ Interventional™ Hemostatic Bandage, no slit with 3M Tegaderm™	183	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ Interventional™ Hemostatic Bandage, pre-slit with 3M Tegaderm™	188	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ Combat Gauze™ Z-Fold	200	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ Combat Gauze™ TraumaPad™	210	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ Combat Gauze™ (German)	289	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ 2x2 Hemostatic Dressing	302	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ 4 x 4 Hemostatic Dressing	301	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ TraumaPad™	303	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787

QuikClot™ Combat Gauze™ XL	345	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ Combat Gauze™ LE	350	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ Interventional™ Hemostatic Bandage, no slit	467Z	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ EMS Rolled Gauze	475	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ Z-Fold Hemostatic Dressing	632	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ Roll Hemostatic Dressing	633	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787
QuikClot™ EMS 4x4 Dressing	636	CE 697147 CE 508609	26-May-2024	31-Dec-2027	III	Rule 14	Annex IX, Chapter I and III	n/a	19-Dec-2022	Q390897 Q661787