EUROPEAN AUTHORIZED REPRESENTATIVE AGREEMENT FOR MEDICAL DEVICES

This is an agreement (together with Annexes 1-5 attached hereto, the ‘‘AGREEMENT’’) made this day, February DD, 2020, and effective as from April 01, 2020, by and between “MANUFACTURER”, a company organized and existing under the laws of the state of STATE, COUNTRY, with offices ---------- , (‘‘MANUFACTURER’’), and MediMark Europe Sarl., a company organized and existing under the laws of France with offices at : 11 rue Emile ZOLA, B.P. 2332 , 38033 GRENOBLE CEDEX 2, FRANCE (‘‘AUTHORIZED REPRESENTATIVE’’).

In consideration of the mutual promises and conditions herein contained, the parties hereto agree as follows:

1.0. APPOINTMENT

1.1. MANUFACTURER hereby appoints MediMark Europe Sarl upon the terms and conditions herein contained to be MANUFACTURER’s AUTHORIZED REPRESENTATIVE with regards to the Directive 93/42/EEC until May 26th 2021 and starting on May 27th 2021 to the Medical Devices Regulation (2017/745/EU) (MDR) in European Economic Area of those products set forth on the Product List appended in Annex 1 hereto (the ‘‘PRODUCTS’’). PRODUCTS may be added or re-added or removed to the above Product List only by written amendment delivered by MANUFACTURER to AUTHORIZED REPRESENTATIVE and agreed in writing by AUTHORIZED REPRESENTATIVE. It is understood and agreed that MANUFACTURER (and its affiliates) may discontinue manufacture of any of the PRODUCTS without obligation to AUTHORIZED REPRESENTATIVE except a 3-month written notification.

2.0. AUTHORIZED REPRESENTATIVE’S ACTIVITIES AND RESPONSIBILITIES

AUTHORIZED REPRESENTATIVE takes the engagement to answer to the requirements of the Article 11 of the Medical Devices Regulation 2017/745/EU - “Authorised representative no later than May 27th 2021 (See Annex 4 of this agreement)

2.1. AUTHORIZED REPRESENTATIVE shall perform the following task:

(a) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available a copy of the PRODUCTS technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificates, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities;

(c) comply with the registration obligations laid down in the Directive 93/42/EEC and then in the MDR and verify that MANUFACTURER has complied with its own registration obligations laid down in the MDR;

(d) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

(e) forward to MANUFACTURER any request by a competent authority of the Member State in which AUTHORIZED REPRESENTATIVE has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

(f) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform MANUFACTURER about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

(h) In case of incidents known first by t MANUFACTURER, AUTHORIZED REPRESENTATIVE will be immediately informed and will immediately perform with MANUFACTURER the analysis of the incident. If considered as reportable AUTHORIZED REPRESENTATIVE will write and send to the concerned Competent Authority, within the time lines defined by the applicable regulation, the initial report including MANUFACTURER's actions if available such as sample analysis, analysis of historic lot records and potential corrective actions with target. As soon as incident investigation by MANUFACTURER is completed, AUTHORIZED REPRESENTATIVE writes and sends the final incident report. In any case, AUTHORIZED REPRESENTATIVE submits these reports to MANUFACTURER for preliminary approval. AUTHORIZED REPRESENTATIVE will keep these records available for inspection by competent authorities;

(i) In case of Field Safety Corrective Action (FSCA) decided by MANUFACTURER, AUTHORIZED REPRESENTATIVE will request all the necessary information allowing FSCA initial reporting to the concerned competent authorities. AUTHORIZED REPRESENTATIVE will forward to MANUFACTURER any request from the concerned competent authorities and will transmit the answers to these competent authorities. As soon as the FSCA is considered as completed by MANUFACTURER, AUTHORIZED REPRESENTATIVE writes and sends the final FSCA report to the concerned competent authorities. In any case, AUTHORIZED REPRESENTATIVE submits these reports to MANUFACTURER for preliminary approval. AUTHORIZED REPRESENTATIVE will keep these records available for inspection by Competent Authorities.

2.2. AUTHORIZED REPRESENTATIVE shall work closely with MANUFACTURER and shall transmit without delay any information coming from competent authorities. In case of special request by competent authorities, particularly in relation with incident reporting or FSCA, AUTHORIZED REPRESENTATIVE will agree with MANUFACTURER on position statement and answers to give to these Authorities.
In case of difference in position between the MANUFACTURER and the AUTHORIZED REPRESENTATIVE, the position of the MANUFACTURER will prevail and will be supplied to the Competent Authorities with a formal endorsement of the Manufacturer

2.3. AUTHORIZED REPRESENTATIVE shall maintain an updated Quality System and communicate the vigilance procedures to MANUFACTURER for coordination and continuity of MANUFACTURER's own Quality System. AUTHORIZED REPRESENTATIVE shall communicate any of other procedures on request of the MANUFACTURER.

2.4. AUTHORIZED REPRESENTATIVE shall allow MANUFACTURER's Notified Body to inspect their premises/operations/QMS, whether this be an announced or unannounced visit. AUTHORIZED REPRESENTATIVE is required to fully collaborate during these visits because their premises/ operations/QMS pertain to regulatory responsibilities for MANUFACTURER. Access must be provided for the visit without unreasonable delay."

3.0. OBLIGATIONS OF MANUFACTURER

3.1. MANUFACTURER takes the engagement to answer to the requirements of the Article 10 of the Medical Devices Regulation 2017/745/EU - "General obligations of manufacturers" no later than May 27th 2021 (See Annex 3 of this agreement)

3.2 MANUFACTURER is obliged to honour all information request from AUTHORIZED REPRESENTATIVE necessary to comply with E.E.A. regulations concerning Medical Devices. MANUFACTURER shall transmit within 48 hours to the AUTHORIZED REPRESENTATIVE any information requested by a Competent Authority**.**

3.3 MANUFACTURER shall inform AUTHORIZED REPRESENTATIVE without delay of any risks of incident(s) and transmit any necessary information to protect patients and users. MANUFACTURER and AUTHORIZED REPRESENTATIVE must be in consensus of position statement for reports and answers to give to Competent Authorities.

3.4 MANUFACTURER shall inform AUTHORIZED REPRESENTATIVE by written notice of any change which should be reported in the Technical File as a proof of compliance with the CE Marking. In case of products are withdrawn from the market, MANUFACTURER shall keep EC Declaration of conformities and Technical Files during a period of ten (10) years or fifteen (15) years for implantable devices after the last products have been made.

3.5 MANUFACTURER will check with AUTHORIZED REPRESENTATIVE to determine whether new claims printed on the labels, packaging, manuals and other documents or materials will change the regulatory status (e.g.: class) of the PRODUCTS and are in compliance with E.E.A. regulations.

3.6 MANUFACTURER shall communicate to AUTHORIZED REPRESENTATIVE the list with address of PRODUCT Distributors established in the E.E.A. and inform by written notice any change in this list.

3.7 MANUFACTURER shall hold appropriate training courses concerning the procedure of incident reporting system for the staff of Authorized Distributors who work with PRODUCTS. 3.7

3.8 MANUFACTURER shall inform AUTHORIZED REPRESENTATIVE by written notice of any clinical investigation performed with PRODUCTS in Europe.
The AUTHORIZED REPRESENTATIVE shall keep the written report with data collected during the clinical investigation at the disposal of the Competent Authorities. In any case AUTHORIZED REPRESENTATIVE can be considered as “Legal representative” for these clinical investigations.

3.9 MANUFACTURER shall proceed to a simulation of product lot recall at least every two years in order to demonstrate their capabilities in term of traceability and Field Safety Corrective Action procedure efficiency.

3.10 Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national laws. MANUFACTURER shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

3.11 Liability insurance of the MANUFACTURER shall also cover for the same financial coverage the liability of AUTHORIZED REPRESENTATIVE for MANUFACTURER product families from an insurance company having direct or indirect offices in the main EU countries including France. A certificate proving the coverage of AUTHORIZED REPRESENTATIVE’s liability shall be supplied at the application date of the contract and then before end of January of each year.

3.12 MANUFACTURER shall pay or reimburse to AUTHORIZED REPRESENTATIVE any additional fees, fines and penalties required by EEA competent authorities or by EEA national Courts of Justice in relation with MANUFACTURER devices, defective devices, vigilance reports, post market surveillance and technical files considered as defective upon inspection by EEA competent authorities.

4. FEES, PAYMENTS AND TRAVEL EXPENSES

4.1 MANUFACTURER shall pay AUTHORIZED REPRESENTATIVE's annual fees at the beginning of each contract term, preferably by bank transfer to MediMark Europe or by bank check if more convenient for MANUFACTURER.

4.2 MANUFACTURER shall reimburse AUTHORIZED REPRESENTATIVE's any registration & other taxes requested by European Member States.

4.3 In case of severe incident(s) conducting to a risk of PRODUCT withdrawal from the E.E.A. market and requiring international travels, AUTHORIZED REPRESENTATIVE will charge travel expenses to MANUFACTURER, after written agreement.

4.4 By April 1st of each year after the first year, AUTHORIZED REPRESENTATIVE will adjust the base fees in Annex 1 on the published previous calendar year annual growth rate of the United States Consumer Prices All items, the changes entering into effect as of the next invoice.

5. DURATION OF AGREEMENT, TERMINATION

5.1 This AGREEMENT shall enter in force on its effective date mentioned above for a period of twelve months (12) and will be prolonged each year for the same period by tacit renewal. This AGREEMENT may be terminated by either party at any date after the first twelve months period by written notification to the other party three (3) months prior the indicated termination date.

5.2 The AGREEMENT may be terminated forthwith by either party for good cause. Any event shall be deemed good cause for immediate termination that would make it unacceptable for the affected party to continue upholding the AGREEMENT until it can be terminated in the ordinary course of business, in particular:

- if the other party ceases rendering payment;
- if the other party continues to be in material breach of the AGREEMENT even after being notified of such breach, and/or fails to remedy the consequences of such breach.
- if the manufacturer acts contrary to its obligations under the MDR.

5.3 As per the Article 12 of the MDR, the detailed arrangements for a change of authorized representative shall be clearly defined in an agreement between MANUFACTURER, the outgoing authorized representative, and where practicable, the incoming authorized representative. That agreement shall address at least the following aspects:
(a) the date of termination of the mandate of the outgoing authorized representative and date of beginning of the mandate of the incoming authorized representative;
(b) the date until which the outgoing authorized representative may be indicated in the information supplied by the manufacturer, including any promotional material;
(c) the transfer of documents, including confidentiality aspects and property rights;
(d) the obligation of the outgoing authorized representative after the end of the mandate to forward to the manufacturer or incoming authorized representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorized representative.

5.4 Any and all claims for indemnification upon termination of this AGREEMENT or its expiration because of the ending of the AGREEMENT shall be excluded.

5.5 Upon termination of the AGREEMENT, AUTHORIZED REPRESENTATIVE is obliged to send to MANUFACTURER all information and advertising materials, all other objects that are the property of the MANUFACTURER, including all other materials concerning the PRODUCTS that may be in its possession except documents which should be kept as requested by laws. AUTHORIZED REPRESENTATIVE has no rights of retention to these whatsoever as a consequence of any justified or alleged claims vis-à-vis MANUFACTURER.

6. INDUSTRIAL PROPERTY RIGHTS

AUTHORIZED REPRESENTATIVE may not assert any claims whatsoever to the industrial property rights associated with the PRODUCTS.

7. WAIVER

7.1 All claims, without exception, made by the parties against one another on the basis of this AGREEMENT must be asserted in writing within twelve (12) months of termination of the AGREEMENT and/or any part thereof, or else they will be forfeited.

7.2 The waiver of or the failure to enforce a right of this AGREEMENT shall not be deemed as general waiver of such right thereafter.

8. GENERAL PROVISIONS

8.1 No oral ancillary agreements have been entered into. Any written or oral agreements by the parties or arrangements practiced by them prior to concluding this AGREEMENT shall be superseded. All changes and amendments to this AGREEMENT shall only be valid if in writing. This shall also apply if the parties wish to change the requirement of written form.

8.2 MANUFACTURER shall have the right to assign this AGREEMENT in whole or in part to an affiliated company, always provided that AUTHORIZED REPRESENTATIVE shall have the right to obtain MANUFACTURER's statement to guarantee for the performance of this AGREEMENT by the affiliated company.

8.3 Should any provision of the present AGREEMENT be invalid; this shall not affect the validity of the AGREEMENT as a whole. In such an event, the parties shall endeavour to replace the invalid provision(s) by new provision(s) of which the economic intent is as closely as possible the same.

8.4 This AGREEMENT is subject to the laws of FRANCE.

AUTHORIZED REPRESENTATIVE: MediMark Europe SARL	MANUFACTURER:
Place : 11 rue Emile ZOLA, BP 2332, 38033 Grenoble Cedex 2, France	Place:
Date: Signature: Name/Title:	Date: Signature: Name/Title:

ANNEX 1 – Option 2

PRODUCT FAMILIES, ANNEX/LIST AND SUB-CATEGORIES Based on permanently updated Declaration_of_Conformity of your devices as per MDR requirements.	ANNUAL ADMINISTRATIVE FEE* (in US $)
PRODUCT FAMILY 1: *Includes 2020 CPI (2.3%).*	**USD ***
(Use additional pages for other families)	
TOTAL ANNUAL ADMINISTRATIVE FEE:	**USD**

(*) Does not include any registration & other taxes requested by European Member States.

TERMS: Payable at the beginning of each year

Preferred method of payment is wire transfer of US funds to:

Bank: CREDIT LYONNAIS, Parc Exposition, 38000 Grenoble, France.
Account Owner: MEDIMARK EUROPE SARL

International Bank Account Number: FR82 3000 2026 4200 0007 1089 W35
Swift code / Bank Identifier Code: CRLYFRPP

CAUTION: BANK ACCOUNT IS IN US $

The annual Administrative fee includes:

- **Use of MediMark® Europe name and address for CE Mark Labeling;**
- **Operational assistance in designing multilingual label in compliance with the Medical Devices Regulations;**
- **Electronic documents for building of technical files;**
- **Reviews technical file and maintains a copy of the full Technical File at disposal of competent authorities;**
- **Makes Notifications of Class 1, 2a, 2b and 3 devices to ANSM, the French Competent Authority and when EUDAMED database becomes effective, adds its EAR approval for the agreed device list entered by the Manufacturer into EUDAMED.**

- **Consulting for initial compliance and maintenance of compliance in regards to the above activities. Permanent hot line for advises about Regulatory Affairs in Europe. Supply of European regulatory documents and free access to the Section "Members" of MME website.**
- **Free access to a private Manufacturer's space in MediMark Europe's server allowing quick easy and secure downloads of Technical files.**

The Vigilance Fees are as follows:

Type of Incident	Maximum Fee*
• Incident assessment - Conclusion: Not reportable	Ten first free $ 300 per assessment after the 10th
• Non severe reportable incident or official answer report to Competent Authority questions	Up to $1150 (see attachment 1)
• Severe Incident (serious deterioration in state of health of a patient). Follow up contacts / meetings with C.A. • Product FSCA/ recall: See Attachment 2	Up to $ 2875 (see attachment 1)

(*) Does not include any related travel expenses made after Manufacturer approval.

TERMS: Payable 3 months after the incident or recall reports are notified.

Preferred method of payment is wire transfer of US funds to:

Bank: CREDIT LYONNAIS, Parc Exposition, 38000 Grenoble, France.
Account Owner: MEDIMARK EUROPE SARL.

International Bank Account Number: FR82 3000 2026 4200 0007 1089 W35
Swift code / Bank Identifier Code: CRLYFRPP.

CAUTION: BANK ACCOUNT IS IN US $

Attachment 1: Fees for Incidents

Type of vigilance report	Fee	Comments
Sending a combined report without additional questions from NCA - No severe health consequences	$ 750	
Sending initial and final reports without additional questions from NCA - No severe health consequences	$ 850	
Sending initial and final reports with usual questions from NCA – No severe health consequences	$ 950	

Sending initial and final reports with usual + 1 or 2 letters for additional questions from NCA – No severe health consequences	**$ 1150**	**Maximum $1150**
Sending a combined report without additional questions from NCA - Severe health consequences	**$ 750**	
Sending initial and final reports without additional questions from NCA - Severe health consequences	**$ 850**	
Sending initial and final reports with usual questions from NCA - Severe health consequences	**$ 950**	
Sending initial and final reports with usual + 1 letter for additional questions from NCA - Severe health consequences	**$ 1150**	
Sending initial and final reports with usual + 2 letters for additional questions from NCA - Severe health consequences	**$ 1350**	
Then $ 200 for each additional request from NCA		**Maximum $ 2875**

Attachment 2: Fees for Product FSCA / Recall

COUNTRY	**FEES****	**REMARKS**
Republic of Ireland	**1500 $**	**FSCA usually conducts to multiple transactions with the Irish competent authority**
UK (to be revised after Brexit output)	**1300 $**	**Regular FSCA follow-up requested by MHRA**
Germany	**1200 $**	**FSCA follow-up of the CAPA requested by BfArM**
France	**1200 $**	**FSCA NCA Coordinator follow-up requested by ANSM**
Others	**800 $**	**FSCA close follow-up**

(**) Does not include any travel expenses for recall activities.

These fees can be subject to changes based on any modifications to individual country requirements

AUTHORIZED REPRESENTATIVE: MediMark Europe SARL	MANUFACTURER:
Place : 11 rue Emile ZOLA, BP 2332, 38033 Grenoble Cedex 2, France	Place:
Date: Signature: Name/Title:	Date: Signature: Name/Title:

Attachment 3: Article 10 of the MDR 2017/745/EU

Article 10 **General obligations of manufacturers:**

1.When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

2.Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.

3.Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.

4.Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III. The Commission is empowered to adopt delegated acts in accordance with Article 115 amending, in the light of technical progress, the Annexes II and III

5.Manufacturers of custom-made devices shall draw up, keep up to date and keep available for Competent Authorities documentation in accordance with Section 2 of Annex XIII

6.Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity in accordance with Article 19, and affix the CE marking of conformity in accordance with Article 20.

7.Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31.

8.Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market. Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof. A manufacturer with a registered place of business outside the Union shall, in order to allow its authorized representative to fulfil the tasks mentioned in Article 11(3), ensure that the authorized representative has the necessary documentation permanently available.

9.Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonized standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner. Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device. The quality management system shall cover all parts and elements of a manufacturer's organization dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation. The quality management system shall address at least the following aspects:

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

(b) identification of applicable general safety and performance requirements and exploration of options to address those requirements;

(c) responsibility of the management;

(d) resource management, including selection and control of suppliers and sub-contractors; (e) risk management as set out in in Section 3 of Annex I;

(f) clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;

(g) product realization, including planning, design, development, production and service provision;

(h) verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29;

(i) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83;

(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

(l) management of corrective and preventive actions and verification of their effectiveness;

(m) processes for monitoring and measurement of output, data analysis and product improvement.

10.Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 83.

11.Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

12.Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorized representative and importers accordingly. Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56, in particular, of the non-compliance and of any corrective action taken.

13.Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88

14.Manufacturers shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authority of the Member State in which the manufacturer has its registered place of business may require that the manufacturer provide samples of the device free of charge or, where that is impracticable, grant access to the device. Manufacturers shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service. If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may, in order to ensure the protection of public health

and patient safety, take all appropriate measures to prohibit or restrict the device's being made available on its national market, to withdraw the device from that market or to recall it until the manufacturer cooperates or provides complete and correct information. If a competent authority considers or has reason to believe that a device has caused damage, it shall, upon request, facilitate the provision of the information and documentation referred to in the first subparagraph to the potentially injured patient or user and, as appropriate, the patient's or user's successor in title, the patient's or user's health insurance company or other third parties affected by the damage caused to the patient or user, without prejudice to data protection rules and, unless there is an overriding public interest in disclosure, without prejudice to the protection of intellectual property rights. The competent authority need not comply with the obligation laid down in the third subparagraph where disclosure of the information and documentation referred to in the first subparagraph is ordinarily dealt with in the context of legal proceedings.

15.Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 29(4).

16.Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law. Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

Attachment 4: Article 11 of the MDR 2017/745/EU

Article 11 **Authorized representative:**

1.Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorized representative.

2.The designation shall constitute the authorized representative's mandate. It shall be valid only when accepted in writing by the authorized representative and shall be effective at least for all devices of the same generic device group.

3.The authorized representative shall perform the tasks specified in the mandate agreed between it and the manufacturer. The authorized representative shall provide a copy of the mandate to the competent authority, upon request.

The mandate shall require, and the manufacturer shall enable, the authorized representative to perform at least the following tasks in relation to the devices that it covers:

(a) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

(c) comply with the registration obligations laid down in Article 31 and verify that the manufacturer has complied with the registration obligations laid down in Articles 27 and 29; 5.5.2017 L 117/25 Official Journal of the European Union EN

(d) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

(e)forward to the manufacturer any request by a competent authority of the Member State in which the authorized representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

(f) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

(h) terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.

4.The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11) and (12).

5.Without prejudice to paragraph 4 of this Article, where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorized representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

6.An authorized representative who terminates its mandate on the ground referred to in point (h) of paragraph 3 shall immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

7.Any reference in this Regulation to the competent authority of the Member State in which the manufacturer has its registered place of business shall be understood as a reference to the competent authority of the Member State in which the authorized representative, designated by a manufacturer referred to in paragraph 1, has its registered place of business.

Attachment 5: Declaration of Conformity