**MANUFACTURER’S MANDATE FOR TRANSLATION**

**THIS AGREEMENT** (hereinafter: “**Agreement**”) is concluded on [xx].

**BETWEEN:**

**[xx]**  with its registered office in [xx], entered into the official company register under number [xx], tax identification number: [xx] (hereinafter: ”**Manufacturer**"), duly represented by:

[xx] – [xx]

[xx] – [xx]

and

**[xx]** with its registered office in [xx], entered in the official KRS register under number [xx], tax identification number (NIP): [xx], (hereinafter: “**Distributor**”), duly represented by:

[xx] – [xx]

[xx] – [xx]

hereinafter individually referred to as "**Party**” or collectively as the "**Parties**”.

**WHEREAS:**

1. The Manufacturer produces [xx] medical device (hereinafter: “**Device**”) in the meaning of art. 2 (30) of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter: “**MDR**”).
2. The Parties concluded an agreement for distribution of the Device in the territory of Poland.
3. Under Polish law, Device may be made available to Polish lay users on condition all obligatory text information, including IFU (where applicable) and labelling, supplied with Device in accordance with Section 23 of Annex I of MDR (hereinafter: “**Information**”), are in Polish.
4. The Parties wish to avoid situation where the Distributor is deemed an entity performing independently, in its own right and on its own behalf, activities referred to art. 16 sec. 2 and 3 of MDR.

**IT IS AGREED AS FOLLOWS:**

**§1**

1. The Manufacturer mandates and the Distributor accepts the mandate to translate and provide all Information supplied with Device in Polish language.
2. The Parties agree that:
	1. the Distributor shall translate Information by means of obtaining professional translation service ensuring appropriate skills, knowledge and experience in the corresponding field;
	2. the translations shall be provided to the Manufacturer for validation;
	3. Manufacturer shall validate the translations and inform the Distributor of positive validation or request further changes;
	4. after positive validation of the translations, the Distributor shall provide the translated Information on/with Device.

**§2**

1. The Manufacturer represents that the activities mandated to the Distributor result from and are in compliance with the quality management system covering production of Device.
2. The activities to be performed under this Agreement are made on behalf of the Manufacturer.
3. The Distributor shall not bear any risk or liability versus third parties for the activities performed under this Agreement and shall not be deemed manufacturer within the meaning of art. 2 point 30 of MDR, nor entity referred to in art. 16 sec. 2 and of MDR.
4. Neither Party is entitled to any remuneration for the performance of the activities specified in this Agreement.

**§3**

1. Any changes to the Agreement must be made in writing under the pain of nullity.
2. This Agreement shall be governed by the laws of the Republic of Poland.
3. Any dispute, controversy or claim arising out of or in connection with this Agreement, or the breach or violation of its provisions, termination or invalidity thereof, shall be finally settled by the competent common court in Warsaw.
4. This Agreement has been duly executed in two (2) identical originals, each for one of the Parties.

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| **DISTRIBUTOR** | **MANUFACTURER** |