Agreement

concluded by and between

as manufacturer ULTRAGEL MEDICAL Kft, (hereinafter referred to as 'Manufacturer) (1022 Budapest, Aranka u. 12. Hungary)
and

as distributor A. Zapalskio Į "AZAS" hereinafter referred to as 'Distributor') Tiekimo g. 2 A, Panevėžys 35100, Lithuania.

Manufacturer and Distributor hereinafter referred to as 'Contracting Parties' or 'Parties'

in accordance with 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) No178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter referred to as 'MDR regulation') in order to take the necessary steps to remain in the market.

Considering the fact that Distributor is making available the device of Manufacturer on the Union Market, Contracting Parties agree as follows:

1. Introductory provisions

(a) Contracting Parties hereby jointly declare that they are acquainted with the provisions of MDR regulation and undertake to cooperate with each other regarding medical devices of Manufacturer marketed by Distributor (hereinafter referred to as 'Device' or 'Devices') in order to comply with the obligations imposed by MDR regulation.

(b) Distributor acknowledges and undertakes to be informed about and perform the obligations prescribed by the provisions of statutory instruments and other requirements of the country where the Devices are marketed at any time regarding his commercial activity (including but not limited to making available the Devices on the market). Furthermore, Distributor shall inform Manufacturer about such provisions and requirements.

(c) Manufacturer declares that the devices manufactured by him qualify as class I. medical devices, in accordance with the 1st rule of Annex VIII. Chapter 3 of MDR regulation.

2. Registration

(a) Manufacturer shall register itself and the devices in the European Union.

(b) If any member state of the EU requires registration of distributors or marketing (making available of the devices) regarding or concerning the Devices, the registration is the obligation of Distributor.

Distributor hereby declares that he is (Please underline the right answer).
obliged / ***not obliged to*** register himself/itself or its activity.

In case of a registration obligation, Distributor shall provide Manufacturer with the documents proving the fulfillment of registration obligation, within 8 days.

3. General provisions

(a) In pursuance of making available the Devices Distributor shall comply with the provisions of applicable laws.

(b) If Manufacturer considers or has reason to believe that any Device is not in conformity with MDR regulation, after having taken the necessary measures it shall inform Distributor without delay. (MDR regulation Article 10. paragraph (12))

(c) Where Distributor considers or has reason to believe that any Device is not in conformity with the requirements of MDR regulation, it shall inform Manufacturer and importer immediately.
Distributor shall not make the Device available on the market until it has been brought into conformity.
(MDR regulation Article 14. paragraph (2))

(d) Distributor shall ensure that, while the Device is under their responsibility, storage or transport conditions comply with the conditions set by Manufacturer and do not jeopardise its compliance with the general safety and performance requirements. (MDR regulation Article 14. paragraph (3))

(e) Distributor shall co-operate with Manufacturer to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, is taken. (MDR regulation Article 14. paragraph (4))

(f) If Distributor receives complaints or reports from healthcare professionals, patients or users about suspected incidents related to any Device it has made available, shall immediately forward this information to Manufacturer.
Distributor shall keep a register of complaints, of non-conforming Devices and of recalls and withdrawals, and keep Manufacturer informed of such monitoring and provide it with any information upon its request. (MDR regulation Article 14. paragraph (5))

(g) Distributor shall, upon request by a competent authority, provide it with all the information and documentation that is at his disposal and is necessary to demonstrate the conformity of a Device. (MDR regulation Article 14. paragraph (6))

4. Identification within the supply chain

(a) Distributor shall co-operate with Manufacturer to achieve an appropriate level of traceability of Devices. (MDR regulation Article 25. paragraph (1))

(b) Distributor shall keep a register of
a) any economic operator to whom they have directly supplied a Device;
b) any economic operator who has directly supplied them with a Device;
c) any health institution or healthcare professional to which they have directly supplied a Device.
(MDR regulation Article 25. paragraph (2))

(c) Distributor shall, upon request, provide Manufacturer with information which may be only denied in justified cases. Manufacturer undertakes that he does not use this information provided for its own (direct sales) purposes.

5. Special provisions

(a) The label of the Device shall be supplied by Manufacturer (hereinafter referred to as the label of Manufacturer) in accordance with MDR regulation (MDR regulation Annex I point 23.)

(b) The Distributors who make or want to make available the products of Manufacturer labelled with an unique label (unique label means any label which differs from the Manufacturer's official label in any of its properties, for example the name of the device, the language of the text, the distributor has its own product code, design etc) shall notify Manufacturer.

If Parties agree on the form and/or content of the unique label complying with the provisions of MDR regulation, the label will constitute a part of the Technical documentation in the section having the title 'Information to be supplied by the Manufacturer'.

The labelling by the unique label may only be taken place after the fulfillment of the above condition, earliest.

(c) The Instructions for use of the Devices shall be supplied by Manufacturer in one copy to the outer packing of cardboard (one copy in one box) in the previously agreed national language (official Union language) of Distributor established in a member state of EU, identifying Manufacturer as the manufacturer of the Device.
The other necessary copies shall be attached by Distributor after its reproduction in the number of copies required. Distributor is not entitled to alter or modify the Instructions for use in any way.

(d) If Distributor makes available the Devices on other member states of the European Union, he shall fully comply with the provisions of MDR regulation and local law, and he shall attach the accurate translation (to the required official EU language) of the Instructions of use to the Devices.

(e) It is forbidden to alter or modify the content of the information (label, Instructions for use) provided by Manufacturer and to provide third parties any information that are not in accordance with the information supplied by Manufacturer.

(f) If Distributor does not have an own brand or does not market the products with a unique label, Distributor shall use the information provided by Manufacturer (label, Instructions for use).

(g) Distributor acknowledges that if he affixes a label to the Device or to its packaging at his own risk, he is obliged to certify it by a notified conformity assessment body. Distributor shall ensure that any additional label does not obscure any information on the label provided by Manufacturer.

6. Provisions related to post-marketing monitoring.

(a) The Distributor and Manufacturer will concur with each other by sharing the necessary information related to the completion of general safety and operational requirements for the fulfilment of the regulatory obligations of post-marketing monitoring (PMS).

(b) Distributor is obligated to provide information via e-mail at least once a year in 30 days that requested by the Manufacturer .
Parties acknowledge that they have read and understand this Agreement and sign it as the true expression of their will.

Signed on 2022.09.29.

Ultragel Medical Kft.
1022 Budapest, Aranka u. 12.
Adószám: 27751015-2-42

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manufacturer

Signed on .....

A. Zapalskio II
„Azas"
Nr. 2
Direktorius
Juozas Devizis

.....
distributor