Gynetics Medical Products n.v.
Rembert Dodoensstraat 51
3920 Lommel
Belgium

tel: +32 11 64 58 72
fax: +32 11 64 06 77
email: info@gynetics.be
website: www.gynetics.be

Bank Name: KBC Neerpelt
IBAN: BE10 4585 0232 6104
Swift Code: KREDBEBB
VAT: BE 0412.701.841

GYNETICS
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DISTRIBUTOR AGREEMENT

between

Gynétics Medical Products N.V., Rembert Dodoensstraat 51, B-3920 Lommel

(hereinafter "**GMP**")

and

Mekalasi OY, Ilvestie 3,01900 Nurmijärvi, Finland

(hereinafter referred to as "**Distributor**")

Concerns: REGULATORY, RECALL, COMPLAINTS / ADVERSE EVENTS

REGULATORY

1. DISTRIBUTOR has to provide a copy of their whole sale license to GMP.

2. DISTRIBUTOR has to inform GMP concerning regulatory updates and\or changes of the Competent Authorities.

3. DISTRIBUTOR located in the EU should translate the Instructions for Use (IFU) from English into the local language(s) if not yet available. If the IFU is already available in the local language, DISTRIBUTOR will check the current IFU, copy of the translation has to be send to GMP for approval. GMP informs DISTRIBUTOR if content of IFU changes. If applicable, DISTRIBUTOR should translate these changes into the local language.

4. DISTRIBUTOR informs GMP about received product feedback and market information necessary for the Post Marketing Surveillance process of GMP. DISTRIBUTOR shall cooperate with Manufacturer's requests to review experience gained from devices in the post-production phase, including clinical data, and to implement any necessary corrective action.

5. DISTRIBUTOR shall receive approval of GMP regarding distributor's promotional materials of the products of GMP.
DISTRIBUTOR shall participate in any product and product support training specified by the Manufacturer. DISTRIBUTOR shall provide product training to interested parties as specified by the Manufacturer.

6. DISTRIBUTOR shall not change the product, the label, the IFU, the intended use or (trade) name of the product without written instructions and authorization of GMP.
DISTRIBUTOR shall not put any extra labels on the package without a written approval from GMP

7. DISTRIBUTOR should respect the storage conditions defined at the product labels.
DISTRIBUTOR should not outsource storage of the products to a third party without the written approval of GMP.

8. DISTRIBUTOR shall not initiate or acquire additional approvals from local authorities without written authorization of GMP.

9. DISTRIBUTOR should comply with the principles and guidelines of good distribution practice published by the Commission of the European Communities (92/25/EEC), if applicable.

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10. DISTRIBUTOR shall notify the Manufacturer without delay of any refusal or restriction by a Competent Authority regarding Manufacturer's medical devices.

RECALL

1. DISTRIBUTOR will be informed by GMP about the withdrawal of a product from the market.

2 GMP will transmit following information to DISTRIBUTOR: name of the concerned product and batch number, reason for withdrawal, advice in case of adverse events and evaluation of the risk.

3. DISTRIBUTOR will perform traceability of all distributed products in order to recall the product from the market. For this purpose DISTRIBUTOR shall establish the necessary documentation to perform traceability. These documents can be consulted by GMP.
DISTRIBUTOR will keep traceability information available for a period of 5 (five) years upon distribution, also in the event of termination of the Agreement. Exception is the availability of the traceability information for the Intrauterine contraceptive devices. DISTRIBUTOR will keep this information available for a period of 15 (fifteen) years upon distribution.

4. Withdrawal should be performed by DISTRIBUTOR.

5. Only GMP will inform the authorities according to the appropriate procedures.

6 The withdrawn goods will be treated in an appropriate way by DISTRIBUTOR as instructed by GMP.

COMPLAINTS/ADVERSE EVENTS

1. DISTRIBUTOR will inform GMP about any information about any adverse reaction, incident or complaint of a medical device distributed by the distributor.
DISTRIBUTOR shall forward to Manufacturer copies of any and all written complaints, requests, notifications and/or orders of the Competent Authorities, Notified Bodies, purchasers, clients or third parties to the extent they contain post production information relating to Manufacturer and/or its products.

2. DISTRIBUTOR is responsible for quality assurance and should send a complete report* to GMP.
DISTRIBUTOR shall cooperate in Manufacturer's requests regarding incident investigations and cooperate in Manufacturer's field safety corrective actions.

3. GMP will inform the distributor about all necessary measures for handling the complaint.
GMP will inform the distributor about which products/lot numbers the distributor can send to their customers as a replacement. DISTRIBUTOR will not take any action until instructions are given by GMP.

4.1 DISTRIBUTOR will inform GMP about any error in the text of the leaflet, packaging or medical information that could cause a serious risk for incorrect usage of the device.
4.2 GMP will inform distributor about any error in the text of the leaflet, packaging or medical information that could cause a serious risk for incorrect usage of the device.

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*Information required for complaint / adverse reaction / incident report

a) Medical Device commercial name
b) Kind of device
c) Product number
d) Lot numbers
e) Accessories/associated devices (if applicable)
f) Incident reported by (user/other source) address/tel. nr/date reported
g) Incident date
h) Incident description
i) Outcome (death, deterioration in health, other)

Date: 06/11/2015

Gynétics Medical Products N.V.

Ann Laser
(signature)

Name: Ann Laser

Title: Operational Manager

Gynétics Medical Products n.v.
Rembert Dodoensstraat 51
B-3920 Lommel Belgium
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Date: 13, 11 2015

Mekalasi OY

(signature)

Name: John Ekholm

Title: CEO