# EC-REP AGREEMENT 欧盟授权代表协议书

Template No. ZSL-16-AGR-0001 (Ver. 002) Ref. No. 2020-ZSL0127

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| | *11) 有关的检测及试验的介绍，如临床、电气安全、机械安全、生物学评价、理化性能等，列出相关的报告或验证记录编号,可以以检测报告或基本要求检查表的形式列出*<br>*12) CE 证书复印件*<br>*13) 其它必要的文件*<br>Party A shall inform Party B of any changes in its products as well as any updating and/or modification of the technical files as soon as they occur.<br>当产品发生任何变更，或者技术文件发生更新和修改时，甲方应尽快通知乙方。<br><br>It is agreed by both parties that these records shall be available for inspection upon request of Party B or by the relevant authorities.<br>经双方同意，这些记录应可供乙方或有关当局要求的检验。 |
| 3 | Party A shall keep records of serial numbers and/or production lot numbers for all the products delivered within the European Union in order to assure its traceability. These records shall include the following information:<br>甲方应保存所有在欧洲销售的产品批号，以保证可追溯性。内容包括：<br>• Name and address of the distributor / customer 客户地址<br>• Product name and specification 产品名称和说明<br>• Quantity dispatched / delivered 销售数量<br>• Date of transfer to distributor / customer 交货时间<br>• Serial or manufacturing lot numbers 生产批号<br>Both parties agree that these records shall be available for inspection upon request by Party B or by relevant authorities<br>经双方同意，这些记录应可供乙方或有关当局要求的检验。 |
| 4 | In case of any kind incident with the products occurs within the European Union (also including severe adverse event during clinical investigation or study in premarket stage, (refer to clause A1.5 of "Guideline for Authorized Representatives (MEDDEV 2.5/10), Party A shall immediately inform Party B in a working day, providing a complete report of the investigation, analysis and results by email or any other valid way that assures its reception by Party B.<br>Party A shall help to investigate the cause of such incident on time and complete the initial report together with Party B.<br>Party A shall handle the investigation result and final report to Party B in time and form as requested by the vigilance system.<br>In case of any incident with the products occurs outside the EU, Party A shall immediately inform Party B and make the decision whether to report it to competent authorities in the EU. In any case Party B is not responsibility for any incident that takes place outside the EU.<br>如果产品在欧盟境内发生任何事故（包括在上市前临床调查阶段发生的严重不良事件(详见"Guideline for Authorized Representatives (MEDDEV 2.5/10)"），甲方须在一个工作日内转告 |

Zoustech S.L.
Pso. Castellana 141 Pl. 19
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Spain

# Declaration of Conformity

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| Manufacturer: | Guangzhou AMK Medical Equipment Co.,Ltd.<br>No. B13 and B14, Huachuang Industry Park, Jinshan Cun, Shiqi Town, Panyu District, 511450 Guangzhou, PEOPLE' S REPUBLIC OF CHINA |
| European Representative: | **ZOUSTECH S.L.**<br>Pso. Castellana,141–Planta 19, 28046–Madrid, SPAIN |
| Product Name | Surgical Mask（Non-sterile） |
| Model Number: | Ear hanging Type 17.5×9.5cm |
| UMDNS-Code: | 12447 |

Classification (MDD, Annex IX): Class I Rule 1

Conformity Assessment Route: **Annex VII**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Manufacturer takes full responsibility of the content of Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC modified with the Directive 2007/47

Signature:

Name: Yang Linmin

Place& Date: Guangzhou 2020-05-18

Position: GM