MedPath GmbH, Mies-van-der-Rohe-Straße 8, 80807 Munich, Germany

To whom it may concern

MedPath GmbH

Mies-van-der-Rohe-Straße 8
80807 Munich, Germany

Tel: +49(0)89 189174474
Fax: +49(0)89 5485 8884
EMail: info@medpath.pro

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声明
关于德国 DIMDI 系统注册号码

与此声明一起，您已收到贵司产品在德国医学文件信息局（DIMDI）系统中的备案证明文件。至此，相关法规要求已被满足，此产品已可以销往欧洲。向您祝贺，并祝愿商业成功！

请注意此备案证明文件中，第一页 Registration Number（注册号码）目前还是空缺。然而，此注册号码跟市场准入是没有关系的，即贵司的产品已经可以开始在欧洲销售。这是德国医疗器械法（MPG）第 25 条，及 DIMDI 条例（DIMDIV）第 2 条的规定。

Statement
concerning registration No. in German DIMDI System

Together with this statement, please receive the notification document which indicates your device has been notified in German Institute of Medical Documentation and Information (DIMDI) system. Till now, relevant regulatory requirements have been fulfilled, and the device can be put into service in Europe. MedPath wishes you success in business!

Please note that at this point in time, the registration number on the first page of this notification document, is not available yet. However, this registration number is NOT related to market entrance permission in Europe. With the notification document (even no registration number on it yet), the respective product can already be put into service in Europe, according to *German Act on Medical Devices (MPG)§25*, and *German Institute of Medical Documentation and Information Ordinance (DIMDIV)§2*.

之后，德国主管当局会分配注册号码，并填写进欧洲主管当局的自用系统，以及 DIMDI 系统中，使贵公司的备案能在所有系统中被检索到。这个过程可能持续几天到数月不等。待注册号码更新后，我司会立即将带有注册号码的备案证明文件发给您。再次提醒，您不必等待此号码发放之后才启动欧洲的销售。

The German Competent Authority will assign a registration number to this notification, so that it can be retrieved in another digital system used by the European Competent Authorities and DIMDI system, within several days up to months. After this registration number is available, MedPath will send you the updated notification document (with the registration number on it) as soon as possible. Again, you do not have to wait for this registration number to initiate sales in Europe.

当此注册码发放以后，欧盟内用户可以在付费的基础上，在 DIMDI 系统的医疗器械数据库中检索到此备案。（https://www.dimdi.de/dynamic/en/medical-devices/database-search/index.html）

After the registration number is assigned, the notification can be retrieved in DIMDI system against payment for customers within EU. (https://www.dimdi.de/dynamic/en/medical-devices/database-search/index.html)

请注意此备案文件是重要的法规文件，在跟主管当局沟通时，请提供此文件。在收到带有注册号码的备案文件之前，可以使用此文件右上角的 8 位 Formularnummer（表单号）进行识别。

Please be aware that this notification document is important for communication with the Competent Authorities. Before the registration number is assigned, please use the 8-digit "Formularnummer" (form number) for identification of the notification.

如果您有任何问题，请直接联系我司，或者负责的德国主管当局。您可以在备案证明文件的第一页看到负责的主管当局的联系方式。

If you have any further questions, please feel free to contact MedPath. You may also contact our responsible Competent Authority. You can find the contact information on the first page of the notification document.

德国医通有限责任公司

MedPath GmbH

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

MedPath GmbH
Mies-van-der-Rohe-Straße 8
80807 München

St.Nr.: 143/161/40603
Ust-IdNr.: DE313841775
HRB 235061

BANK: Postbank
IBAN: DE06 7601 0085 0134 4418 55
BIC: PBNKDEFF