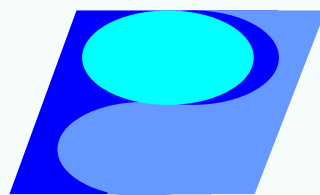


# Outsourcing

MAH (DMAH) duties for  
medical devices and medical supplies.

EPJ MEDICAL SERVICE CO., LTD.



# Outsourcing the MAH duties for medical devices and medical supplies.

## MAH Service (Marketing Approval Holder)

On behalf of foreign manufacturers which don't have any MAH license in Japan, we fulfill the MAH duties as an outsource.

Since foreign manufacturers can not obtain a license as a MAH, foreign manufacturers must appoint a Japanese company which has an appropriate MAH license.

Foreign manufacturers with no business establishments in Japan must appoint a MAH or a designated MAH (D-MAH) to manage their device registrations.

The designated MAH is called D-MAH.  
(Designated Marketing Approval Holder)

### Benefits of the D-MAH Services

- \* Foreign manufacturers become the owner of the approval/certification and they can control the registration of their medical devices.
- \* If foreign manufacturer wants to change their D-MAH, it is an easier process compared to changing MAH.
- \* If you choose D-MAH services, you can solve complicated MAH problems, such as human resource requirements, quality control by QMS (Quality Management System) development and safety management after marketing. Thus, you can significantly reduce the costs and time loss.

$$\text{D-MAH fee} = \text{Monthly fee (D-MAH license fee)} + \text{Inspection fee}$$

## EPJ Medical Service Co., Ltd.

ISO13485:2016 Certification company  
First class marketing license for medical devices (No: 13B1X10004)  
Medical device manufacturer (warehouse) registration (No: 13BZ200973)  
Second class marketing license for veterinary medical devices (No: 30製販療Ⅱ第202号)  
Veterinary medical device manufacturer (warehouse) registration (No: 30製造療第609号)

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(group company) EXPARTNER JAPAN Co., Ltd.

<http://www.expartner-j.co.jp/>

### Product Examples That We Act as a DMAH

ECG Monitor (US)

Dental Implant (Korea)

Surgical forceps (France)

Multiparameter monitor (China)

Pulse Oximeter (China)

Ultrasound diagnostic imaging (China)

Electronic stethoscope (Korea)

Orthopedic Implants (US)

Single-use needle (Korea)

Ultrasonic Surgical Aspirator (US)