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EUROPEAN MEDICAL DEVICE MANUFA
FACE NEW REGULATIONS STARTING I
ACCORDING TO TOP COMPLIANCE CO[illegible]

Maetrics' European Managing Director Outlines
The Demands And Costs Of Implementation,
At Med-Tech Innovation Expo.

(Coventry, UK) "Although there is a great deal of debate still occurring throughout Europe's political and medical device communities, it is virtually certain that comprehensive new medical device regulations will soon be adopted for implementation in 2016," according to Peter Rose, Managing Director of Maetrics Ltd, the European operations of global life sciences consulting firm, Maetrics. According to Rose, "Manufacturers need to start planning now to be ready to comply by the end of 2016."

Rose outlined a number of the key areas covered in these new regulations, during a leading European medical device conference, Med-Tech Innovation Expo, recently held in Coventry, UK:

- Reclassification of certain devices
- Single use devices and reprocessing
- Invasive/implantable devices without a medical purpose
- Qualified Person
- Unique Device Identifier (UDI) and traceability
- Vigilance System

Said Rose, "A common thread will be the standardization of regulations and the centralization of information through the EUDAMED database, even though many of those details are still being finalized." He feels that it has always been a goal of the European Union to update the Directives to take into account new technology (nanotechnology, IVD tests) and streamline the "messy" patchwork of regulations. However, now that these changes are at hand, Mr. Rose says that many European medical device manufacturers have underestimated the planning and expertise needed to modify policies and procedures. Complying with the new regulations will involve cross-department and multi-function planning, including collaborating with suppliers and distributors. "To successfully implement and comply with the new regulations, it requires an experienced team with global reach to manage time, money and resources. Failure to comply risks notifications, fines, recalls and other sanctions from regulators." said Rose.

Now in its thirtieth year, Maetrics is a leading global life science consulting firm specializing in:

- enterprise compliance services
- performance improvement
- risk management
- organizational change management
- information technology

for top-tier pharmaceutical, biotech, medical device companies. The company's headquarters is in Indianapolis, Indiana, USA, and it supports its global client base through offices worldwide.

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