MELAG Medizintechnik oHG
Geneststraße 6-10
D - 10829 Berlin

Tel.: +49 30 75 79 11 - 0
Fax: +49 30 75 79 11 99

E-mail: info@melag.de
Web: www.melag.de

MELAG Medizintechnik oHG Geneststraße 6-10 D - 10829 Berlin

TO WHOM IT MAY CONCERN

Your reference	Your message dated	Our reference	Date
Ceasing of ISO 9001			01.08.2018

For many years MELAG has maintained a Quality management system according to the international standards ISO 9001 and ISO 13485. Both are certified by TÜV Rheinland LGA Product GmbH, one of the world's leading certification bodies.

ISO 9001 is a Quality Management System (QMS) designed to be suitable for organizations in a variety of sectors. ISO 13485 on the other hand includes additional requirements focusing specifically on medical device companies.

With the launch of the latest version of ISO 9001:2015 the standard has undergone significant amendments leading to a divergence from its original structure whilst ISO 13485 remains the same.

These developments led us, like many other organizations within the medical device industry, to the decision to cease accreditation to ISO 9001 and continue solely with ISO 13485.

ISO 13485 is a globally recognized QMS specifically developed for the design and manufacture of medical devices and is aligned to a majority of international regulatory requirements.

Yours sincerely

MELAG Medizintechnik

Digitally signed by Moldoveanu Ruxanda
Date: 2022.03.16 20:10:37 EET
Reason: MoldSign Signature
Location: Moldova

Christoph Sandow
Director International Sales