

Certificate Biological Safety e.chi Energy-Cell



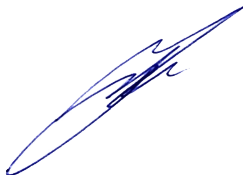
Manufacturer: GEONADO GmbH
Amseltalweg 26
6336 Langkampfen
Austria

Project: STUY421AA0102-1

Sterility: Non-sterile

Biological Risk Assessment: Based upon the requirements of ISO 10993-1:2018 and the FDA Guidance document "Use of International Standard ISO 10993-1", 2020, the overall biological risk assessment of the medical device "e.chi Energy-Cell" was performed. Within this overall biological risk assessment, the requirements for the device considered taking into account the intended use of the device under evaluation.

Considering all study results collected and summarized within the biological risk assessment (Eurofins Medical Device Consulting Statement No. STUY421AA0102-1), the evaluation arguments and considering the provisions of the relevant biological evaluation standards and documents, it is concluded that the medical device "e.chi Energy-Cell" has an acceptable risk. Therefore, the medical device "e.chi Energy-Cell" can be evaluated as biocompatible. This conclusion is valid as long as the devices are manufactured appropriately and used in compliance with the intended use of the device.



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