

October 21, 2022

### EN ISO 13485 Certificate Status

Maxtec, LLC's Quality Management System was subject to an EN ISO 13485:2016/MDSAP Recertification Audit on October 2021. The audit was executed and the audit team made a positive recommendation for certification to the certification body.

Maxtec is awaiting the certification body to finalize the review of the audit before completing Maxtec's recertification. The certification body is experiencing a backlog. As a result, there has been a delay in review of Maxtec's audit and issuance of our certificate.

Maxtec has received a Bridge Letter from our Notified Body regarding our positive recommendation. Refer to "Maxtec EN ISO 13485:2016 Recertification Audit" for more details.

Please contact [quality@maxtec.com](mailto:quality@maxtec.com) for any additional questions.

Sincerely,

Michelle Sanchez

Regulatory and Quality Systems Specialist