

Document Maxtec EyeMax EC Declaration of Conformance Medical Revision ID56121

Suggested Upload Document Name: **Risk Assesment For Updating Document ID56121**
Completed by [Steve Nixon](#) 22 Nov 2021

Reason for Risk Assesment

EU REP change from QNET BV to Emergo Europe

Document Maxtec EyeMax EC Declaration of Conformance Medical Revision ID56121 Is linked to the Following Standards and processes

Risk Assessment Question ID56121		Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further on Issue
56121Q0	Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does Update Affect? <div>No</div>	Risk Frequency due to Update <div>1.Improbable</div> Risk Likly Due to Update <div>1.Negligible</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further on Issue <div></div>
56121Q1	Does Maxtec EyeMax Technical file #108 Of type 3 require any Notificaions and/or Risk assesment updates	Does Update Affect? <div>Yes</div>	Risk Frequency due to Update <div>1.Improbable</div> Risk Likly Due to Update <div>1.Negligible</div> Action Required: Needs Setting	Notes On Risk / Benefits statement if required Some residual stock may refer to QNET BV in the short term. <div></div>	Further on Issue <div></div>
56121Q2	Final Notes No risk to product. <div></div>				

SAVE FORM