Overall Residual Risk - How to Evaluate it ?

The **risk management standard** ISO 14971:2019 is the Holy Bible for medical device risk management. As elegant as it has been presented on its own, one could consider it as ISO's tip of the hat to acknowledge Regulation (EU) 2017/745, the EU MDR. As a successor to ISO 14971:2007, the updated standard has introduced crisp clarifications on previously defined concepts and even restructured certain requirements, aiming for a better fit. We recommend you to check it out your risk management.