Haag-Streit UK is dedicated to meeting new European MDR requirements

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October 2021 - Haag-Streit UK (HS-UK), the leading manufacturer and distributor of gold-standard optometry and ophthalmic equipment, is dedicated to meeting the requirements of the new European Medical Device Regulation (MDR) for all of its products.

HS-UK products are currently certified by the European Medical Device Directive (MDD), and this certification will be valid until May 2024. Following this, all products will then need to be certified under the new MDR requirements. HS-UK products covered by the MDD include the; Synoptophore (major amblyoscope), Perkins Mk3 hand-held applanation tonometer, RAF Gauge and Tonosafe disposable tonometer prisms.

The new regulations are intended to improve the safety and performance of medical devices in Europe throughout the instrument life cycle. This ensures a higher level of protection for the health of patients and users of the medical devices.

The HS-UK Quality Assurance (QA) Team is currently working through every product's technical file to ensure that it meets the increased MDR requirements. They are also working extremely closely with notified bodies while awaiting designation.

The new MDR requires a far more proactive approach to clinical investigation and post-market surveillance. HS-UK will fully meet this requirement with an increased emphasis on obtaining customer feedback, using this to improve both the quality of products and the service provided.

Kerrie Mouncey, HS-UK Quality Assurance & Regulatory Affairs Manager, commented, "We are working incredibly hard to meet the requirements of the new MDR and to ensure that all regulatory deadlines are fully adhered to. We are currently upskilling staff and improving documentation to guarantee a smooth auditing process."

To find out more about the new Medical Device Regulation please visit the European Commission website. For further information on how HS-UK is working towards these requirements, please email the QA team.

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Scan Me:

Company Contact:

Haag-Streit UK

T. 01279 883807
E. rebecca.seymour@haag-streit.com
W. https://www.haag-streit.com/

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