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Elekta early out in securing MDR certificates for its linac portfolio
Compliance with regulations benefits hospitals and patients by securing market access and avoiding disruption of product deliveries

STOCKHOLM – Elekta (EKTA-B.ST) announced today it has received the EU Medical Device Regulation (EU MDR) certificate for its flagship linear accelerator (linac) portfolio. More than 4,000 Elekta linacs are currently clinical around the world, treating patients with a wide variety of cancers. The MDR certificate applies to the following products, including their components and accessories:

- Versa HD™
- Elekta Synergy®
- Elekta Infinity™

The EU MDR, ratified in May 2017, will become effective in May 2021, followed by a transition period until May 2024. Its purpose is to ensure that medical devices are introduced to and sold on the market within a robust, transparent and sustainable regulatory framework.

Anders Skoglund, Elekta's Vice President Regulatory Affairs & Quality, says: “Elekta believes that the MDR provides a good framework for ensuring that the wellbeing of patients is at the forefront of healthcare in Europe and the rest of the world. We are happy that our stringent attention to patient safety meets or exceeds the criteria for this regulation. Attaining MDR certification has been a challenge for all stakeholders, both at the EU level and for the medical device industry, but Elekta has overcome these challenges every step of the way.”

Maurits Wolleswinkel, President Linac Solutions at Elekta, adds: “As a leading medical device company, we’re proud that Elekta is among the first to guarantee that its customers will be able to continue offering their patients advanced cancer treatment without interruption. More importantly, it supports Elekta’s promise to make quality radiation therapy accessible to all, especially during the Covid-19 pandemic.”

Elekta will continue its certification program to ensure that its advanced precision radiation medicine portfolio will be fully compliant during the MDR transition period.

About Medical Device Regulation
The Medical Devices Regulation 2017/745/EU (MDR) brings EU legislation into line with technical advances, changes in medical science and progress in law making. The EU-MDR is designed to be more stringent than the previous Medical Devices Directives (MDD).

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For further information, please contact:
Mattias Thorsson, Head of Corporate Communications and Public Affairs
Tel: +46 70 865 8012, e-mail: Mattias.Thorsson@elekta.com
Time zone: CET: Central European Time

Raven Canzeri, Global Public Relations Manager, Elekta
Tel: +1 770-670-2524, e-mail: raven.canzeri@elekta.com
Time zone: ET: Eastern Time

About Elekta
For almost five decades, Elekta has been a leader in precision radiation medicine. Our more than 4,000 employees worldwide are committed to ensuring everyone in the world with cancer has access to – and benefits from – more precise, personalized radiotherapy treatments. Headquartered in Stockholm, Sweden, Elekta is listed on NASDAQ Stockholm Exchange.
Visit elekta.com or follow @Elekta on Twitter.