



Press release

SHL Telemedicine files pre-submission with FDA for Over the Counter clearance of SHL's SmartHeart™ full 12 Lead ECG

Tel Aviv/Zurich, 12 January 2021 - SHL Telemedicine Ltd. (SIX Swiss Exchange: SHLTN) ("SHL" or the "Company"), a leading provider and developer of advanced personal telemedicine solutions, announced today that it has filed a pre-submission with the US Food and Drug Administration (FDA) for Over the Counter (OTC) use of its SmartHeart™ full 12 Lead ECG. SmartHeart™ is already FDA cleared and marketed in the US as a „prescription only“ device.

The FDA's Pre-Submission Program (Pre-Sub) allows medical device manufacturers to discuss specific aspects of the regulatory process and requirements with the FDA. In the submission SHL requested a meeting with the FDA to discuss the agency's feedback on the proposed use of SmartHeart™ as OTC device and to determine the appropriate regulatory path.

"In the US alone, there are currently about 6.2 million annual visits to Emergency Departments due to chest pain and related symptoms - the second most common cause of visits, out of which 70% are unnecessary." said Erez Nachtomy, CEO of SHL Telemedicine. "With Over the Counter (OTC) clearance for use of SHL's unique and patented SmartHeart™, for performing full 12 Lead ECG, anytime and from anywhere, SmartHeart™ can be marketed directly to consumers to provide peace of mind and address the unmet need for remote cardiac care, representing an exceptional growth opportunity for SHL in the US market."

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About SHL Telemedicine

SHL Telemedicine is engaged in developing and marketing personal telemedicine systems and the provision of medical call center services, with a focus on cardiovascular and related diseases, to end users and to the healthcare community. SHL Telemedicine offers its services and personal telemedicine devices to subscribers utilizing telephonic and Internet communication technology. SHL is listed on the SIX Swiss Exchange (SHLTN, ISIN: IL0010855885, Security No.: 1128957). For more information, please visit our web site at www.shl-telemedicine.com.

Some of the information contained in this press release contains forward-looking statements. Readers are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those in the forward-looking statements as a result of various factors. SHL Telemedicine undertakes no obligation to publicly update or revise any forward-looking statements.