

To whom it may concern and to
Center for Centralized Public Procurement in Health (CAPCS)
regarding
Tender nr. ocds-b3wdp1-MD1726227245956
Ref: Letter Rg02-4752, 17.12.2024

INFORMATION LETTER

We, STORZ MEDICAL AG, the manufacturer of medical devices for Shock Wave Therapy and Lithotripsy, including lithotripter MODULITH SLK with accessories, with head office and production plant in Lohstampfstrasse 8, 8274 Tägerwilen, Switzerland, hereby confirm that HS30, SAMSUNG ultrasound device, is equipped with software, licenses, settings for integration and synchronization with the MODULITH SLK device. It is delivered in a set with the necessary probes/transducers, requested by the Beneficiary, which are ordered individually from the manufacturer SAMSUNG.

Regarding minimum necessary package for Urology and Lithotripsy we hereby confirm that ultrasound localisation system of lithotripter MODULITH SLK is based on ultrasound system HS30, which is produced by SAMSUNG specially for Urology applications and usage in connection with MODULITH SLK device. So this HS30 ultrasound system is equipped with software, licences, settings and etc. for Urology and extracorporeal lithotripsy procedures.

Therefore it is officially confirmed in Operating Manual of MODULITH SLK, on page 44 chapter 3.7.3, in list of compatible Ultrasound Devices that Ultrasound model HS30 is officially allowed to be operated together with the MODULITH® SLK, and thus HS30 is delivered as integral component of the MODULITH SLK. Moreover integration and usage together of HS30 and Modulith SLK are described in details in Operating manual MODULITH SLK, on page 145 of Chapter 12.

Convex probe 3,5 MHz (2-6 MHz range) for ultrasound localization of the stone is fully compatible with therapy head of Modulith SLK, since therapy head of Modulith SLK is designed to be used with this probe.

In Operating Manual MODULITH SLK (page 44, 145) are listed the models of compatible ultrasound machines like HS30, and all of them have probes for extracorporeal lithotripsy procedures, which are produced for STORZ MEDICAL by Samsung in order to be integrated into MODULITH SLK without separate codes, but in one set for urology and extracorporeal lithotripsy. Thus we fully

confirm the compatibility of the first Convex probe 3,5 MHz (2-6 MHz range) and the compatibility of the second Convex probe 2-8 MHz range with echo-guide and biopsy with MODULITH SLK and HS30.

Additional documents "Setting instructions SAMSUNG HS30 crosshair calibration" and "Validation, Verification and Testing SAMSUNG HS30" and "Declaration According to Medical Device Directive 93/42/EEC, Article 12"(page 3) are attached to this letter as additional proof that HS30 is officially tested and approved to work as integral part of MODULITH SLK.

We hope that this will help in your matter, and we look forward to many more years of fruitful cooperation.

Tägerwilen, Switzerland, December 19, 2024



STORZ MEDICAL AG
Peter Schmid
Director International Sales