

Public declaration regarding the manufacture and use of in-house devices by health institutions

Name of health institution: Center for Surgical Science (CSS) at Zealand University Hospital, Køge

Address: Lykkebækvej 1, 4600 Køge, Denmark

Center for Surgical Science at Zealand University Hospital declares that the devices described in the accompanying table are only manufactured and used in -the health institution- and do meet the applicable general safety and performance requirements (GSPR) of the medical devices Regulation (EU 2017/745). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Date and location:
Wednesday 1 February 2023

Name, function and signature of responsible person:
Ismail Gögenür
Chief Medical Officer, Director of CSS, Professor of Surgery

Device identification: AIS-1 V1.0

Device type: MD

Risk class of the device: IIa

Intended purpose: The AIS-1 is intended to provide clinical decision support to colorectal surgeons at multidisciplinary team conferences and the subsequent surgical consultation and physical examination. The tool is only intended to be used for patients above 18 years at the time of diagnosis, undergoing elective curative intended surgery for colorectal cancer. The tool calculates an estimation of the risk of the individual patient based on a defined set of preoperative risk factors, and provides suggestions for risk stratification to be used in the perioperative planning. The use of the tool is limited to the Department of Surgery, Zealand University Hospital, Denmark.

Applicable GSPR fully met? (Y/N): Yes



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