

## Device Schedule:

**Risk Classification:** Class B near-patient devices

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Basic UDI-DI
cobas® Strep A Nucleic acid test for use on the cobas® Liat® System	07341911190	IVR 0503	<p>The cobas® Strep A nucleic acid test for use on the cobas®Liat® System (cobas® Strep A) is a qualitative in vitro diagnostic test for the detection of Streptococcus pyogenes (Group A β-hemolytic Streptococcus, Strep A) in throat swab specimens from patients with signs and symptoms of pharyngitis.</p> <p>The cobas® Strep A assay utilizes nucleic acid purification and polymerase chain reaction (PCR) technology to detect Streptococcus pyogenes by targeting a segment of the Streptococcus pyogenes genome.</p> <p>The cobas® Strep A nucleic acid test for use on the cobas®Liat® System is intended for near patient testing and use by health professionals.</p>	761333601255AH
cobas® Strep A Quality Control Kit for use on the cobas® Liat® System	07402678190	IVR 0503	External Controls for use with the cobas® Liat® Strep A assay nucleic acid test for use on the cobas®Liat® System (07341911190).	761333601255AF