

## 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
<b>cobas</b> ® Strep A Nucleic acid test for use on the <b>cobas</b> ® Liat® System	07341911190	IVR 0503	<p>The <b>cobas</b>® Strep A nucleic acid test for use on the <b>cobas</b>® Liat® System (<b>cobas</b>® 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 <b>cobas</b>® 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 <b>cobas</b>® Strep A nucleic acid test for use on the <b>cobas</b>® Liat® System is intended for use by health professionals or trained operators who are proficient in using the <b>cobas</b>® Liat® System in Near Patient Testing, Point of Care (POC), or clinical laboratory settings.</p>	761333601256AH
<b>cobas</b> ® Strep A Quality Control Kit for use on the <b>cobas</b> ® Liat® System	07402678190	IVR 0503	External Controls for use with the <b>cobas</b> ® Liat® Strep A assay nucleic acid test for use on the <b>cobas</b> ® Liat® System (07341911190).	761333601255AF