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® Cdiff Nucleic acid test for use on the cobas® Liat® System	07454945190	IVR 0503	The cobas® Cdiff Nucleic acid test for use on the cobas® Liat® System is an automated, qualitative in vitro diagnostic test that uses real-time polymerase chain reaction (PCR) for the detection of the toxin B (tcdB) gene of toxigenic Clostridioides difficile (C. difficile) in unformed (liquid or soft) stool specimens obtained from patients suspected of having C. difficile infection (CDI). The cobas® Cdiff Nucleic acid test for use on the cobas® Liat® System is intended for use as an aid in the diagnosis of CDI in humans in conjunction with clinical and epidemiological risk factors.	761333601981BK
cobas® Cdiff Positive and Negative Control Kit for use on the cobas® Liat® System	07454970190			