

Attachment 1- List of affected products – FSCA 5773

Table 1: List of affected product references

Product Ref.	Product name	GMDN code	GMDN Nomenclature	UDI	EU classification
69-013B	BK VIRUS R-GENE	49849	BK virus (BKV) nucleic acid IVD, kit, nucleic acid technique (NAT)	03573026387761	IVDR (EU) 2017/746 : Class C
69-002B	EBV R-GENE	49653	Epstein-Barr virus (EBV) nucleic acid IVD, kit, nucleic acid technique (NAT)	03573026387648	IVDR (EU) 2017/746 : Class C

Table 2: List of impacted lots per product reference

System	Product	Product Ref.	Lot #	Expiry date	Manufacturing Start and End date
R-GENE®	BK VIRUS R-GENE	69-013B	All Lots starting from: 1009358720	N/A	All lots manufactured starting from 13-SEP-2022
R-GENE®	EBV R-GENE	69-002B	N/A	N/A	N/A