

STERIGEL®

Table 1. Identification of regulatory ambit based on risk

Relative Level of Risk		Where? Place of use		Applied to:	
1	Low	A	Home	H	Human skin
2	Moderate	B	Public venues e.g. school, train station, taxi rank, restaurants	S	Inanimate surface
3	High	C	Health institution, Health professional consulting room		
4	Very High	D	Operating room, Burn ward, ICU		



Regulatory ambit		QUADEX COMMERCIAL (FD&C ACT)					QUADEX PROFESSIONAL (ACT 101)			
		FD&C ACT					Act 101			
Relative Level of Risk ↑	4								Registration as a medical device	
	3					Disinfectant & Germicide	Antiseptic & Germicide	Medical Device (Instrument) Operating Room Disinfectant & Germicide		Registration as a medicine
	2			Disinfectant & Germicide	Antiseptic & Germicide					
	1	Disinfectant	Antiseptic & Germicide							
Place of use		A/S	A/H	B/S	B/H	C/S	C/H	D/S	D/H	
		Place of use					Place of use			
e.g.		Hand wipes					S0	S0		

- Medical Devices Licence Number: 00002774MD
- ISO 13485:2016 Quality Management System.
- Ambit of use: A/H B/H