

# QT WIPEs

**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<br>↑ | 4 |                              |                        |                          |                        |     |                               |     |     |  |
|                             | 3 |                              |                        |                          |                        |     |                               |     |     |  |
|                             | 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                 |                        |                          |                        |     |                               |     |     |  |
| e.g.                        |   | Hand wipes                   |                        |                          |                        |     | S0                            | S0  |     |  |

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