

July 2021

Glycerine Swabsticks Statement

Product Name: Glycerine Swabsticks

Product Code: 1115 – Lemon Flavour
1116 – Blackcurrant Flavour

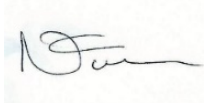
Product Description: Pre-moistened glycerine swabstick

Due to the increasing regulatory demands of the Medical Device Regulation [MDR] (EU) 2017/74 for medical devices and review of the clinical requirements for the Glycerine Swabsticks, Optimum Medical Solutions Ltd has taken the decision not to transition the Glycerine Swabstick product range to MDR.

Since no clinical claims shall be made of the product, the intended use will change from 'relief from discomfort of dry mouth' to 'oral refreshment' and the product will no longer be classified as a medical device. The labelling will reflect this change.

The Glycerine Swabsticks range shall continue to be manufactured and controlled with the same stringent quality processes in place.

Signed on behalf of Optimum Medical:



Nadine Turner
Regulatory and Quality Director

