Hospidex

Declaration of Conformity

We, Hospidex NV,

with registered place of business: Grijpenlaan 23, 3300 Tienen, Belgium,

with SRN N°: BE-MF-000001349

hereby declare under our sole responsibility that the CE marked product to which this declaration relates:

LEMON-SWAB®		
Catalogue N°	*Product name*	*Basic UDI – DI*
HOS-10-4002HD	Lemon-Swab®	542501868LEMONSWAB000007U

With intended purpose: Swabs for oral care

- Has been classified as class I Medical Device following rule 5 of annex VIII of the Medical Device Regulation (EU) 2017/745
- Is in conformity with the General Safety and Performance requirements of annex I and meets the provisions of Medical Device Regulation (EU) 2017/745.

This declaration is made on the basis of

- The technical documentation in accordance with annex II and III of the Medical Device Regulation (EU) 2017/745
- The principles of the certified Hospidex Quality Management System ISO 13485:2016

This certificate is valid for the above mentioned device, bearing the CE mark and originated & manufactured by Hospidex NV, Grijpenlaan 23, 3300 Tienen, Belgium.

Hendrik Seghers

CEO – Managing Director

Hospidex NV

Tienen, Belgium, June 6th , 2021