

Declaration of Conformity

We, Hospidex France SAS,

with registered place of business: 31, Parc du Golf, 350 avenue JRGG de la Lauzière – 13593, Aix en Provence
Cedex – France

With SRN N°: FR-MF-000008923

Hereby declare under our sole responsibility that the CE marked product(s) to which this declaration relates:

ALCO-PREP® - ALCO-SWAB®		
<i>Catalogue N°</i>	<i>Product name</i>	<i>Basic UDI – DI</i>
HOS-610HD	Alco-Prep® Large	542501868ALCOPREPLARGE0AX
HOS-10-3001HD	Alco-Prep® Medium	542501868ALCOPREPMEDIUMD8
HOS-7235HD	Alco-Prep®	542501868ALCOPREPPF0000ZN
HOS-853-500HD	Alco-Prep®	542501868ALCOPREPFR0000ZQ
HOS-10-4300HD	Alco-Swab®	542501868ALCOSWAB000000AC

With intended purpose: Cleansing of the intact skin and non-invasive medical devices

- Have been classified as class I Medical Device following rule 1 of annex VIII of the Medical Device Regulation (EU) 2017/745
- Are in conformity with the General Safety and Performance requirements of annex I and meet 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 France, 31, Parc du Golf, 350 avenue JRGG de la Lauzière – 13593, Aix en Provence Cedex - France in collaboration with Hospidex NV, Grijpenlaan 23 – 3300 Tienen – Belgium.



Hendrik Seghers

CEO – Managing Director

Hospidex France SAS – Hospidex NV

Tienen, Belgium, July 2th, 2021