Hospidex

# 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°: registration pending

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

| ALCO-PREP® - ALCO-SWAB® | | |
|---|---|---|
| *Catalogue N°* | *Product name* | *Basic UDI – DI* |
| 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

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 collabaration with Hospidex NV, Grijpenlaan 23 – 3300 Tienen – Belgium.

Hendrik Seghers
Managing Director - CEO
Hospidex France SAS – Hospidex NV
Tienen, Belgium, May 21st, 202