

EU DECLARATION OF CONFORMITY , ANNEX IV REGULATION (EU) 745/2017

Laboratorios Indas, S.A.U with registered place of business: Pº del Club deportivo, 1 Edificio 18 Planta 1ª Derecha, Parque Empresarial La Finca, 28223 Pozuelo de Alarcón (Madrid) España and factory: Ctra. Portillo a Novés, Km. 1,5- 45519 Novés (Toledo) España.WEB. www.indas.com

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, Laboratorios Indas, S.A.U.

The Medical Devices listed in Annex EU meet the requirements specified in the Regulation (EU) 745/2017.

SRN: ES-MF-000000586 | **Basic UDI-DI:** 8410520PAIBW

Trade name: SABANINDAS, INDASBED, PINGODOCE, DELIPLUS

Risk class: Class I, Annex VIII Rule 1 Regulation (EU) 745/2017

Harmonised standards: EN ISO 15223, EN ISO 10993-1, EN ISO 14971, ISO 11948-1, EN ISO 16021. Management system conforms to the EN ISO 13485 and EN ISO 14001 standards for quality and the environment

Intended Purpose: Light, moderate or heavy incontinence. Clinical Procedures

Declares The Medical Devices, listed in this declaration, achieve the performance intended. The devices have been designed and manufactured in such a way that they comply with the mentioned Regulation, and with the general safety and performance requirements set out in Annex I, which are applicable to the device taking into account its intended purpose and the generally acknowledged state of the art., therefore, during normal conditions of use, they are suitable for their intended purpose. They are safe and effective and will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons

Commits himself to: follow the procedures and meet the requirements specified in the Regulation (EU) 745/2017, and the obligations described in those Annexes that refer to the chosen procedure for production quality assurance; and to establish and keep up to date a systematic procedure for post-production phase and surveillance proportionate to the risk class of the product according to Annex III of Regulation (EU) 745/2017, using appropriate means to implement the necessary safety corrective actions, including effective communication with the competent authorities as soon as serious incidents or significant trends in the frequency or seriousness of incidents become known, in accordance with the manner and within the time limits indicated by that Regulation.



Diego Girón Fernández
Technical Manager
on behalf of **Laboratorios Indas, S.A.U**
Novés, 12-01-2021



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N.I.F. ES A-45002516



Annex EU

BASIC UDI: 8410520PAIBW

| UDI | REF | DESCRIPCIÓN | LOGISTICS PACKAGE |
|----------------|---------|--|-------------------|
| 8410520039213 | 1834011 | SABANINDAS PROTECTOR 60X40cm B30 | BAG |
| 18410520039210 | 1834011 | SABANINDAS PROTECTOR 60X40cm C240 | BOX |
| 8410520039220 | 1834012 | SABANINDAS PROTECTOR 60X60cm B25 | BAG |
| 18410520039227 | 1834012 | SABANINDAS PROTECTOR 60X60cm C150 | BOX |
| 8410520039237 | 1834013 | SABANINDAS PROTECTOR 60X75cm B25 | BAG |
| 18410520039234 | 1834013 | SABANINDAS PROTECTOR 60X75cm C150 | BOX |
| 8410520039145 | 1834014 | SABANINDAS PROTECTOR 60X90cm B25 | BAG |
| 18410520039142 | 1834014 | SABANINDAS PROTECTOR 60X90cm C150 | BOX |
| 8410520039152 | 1834015 | SABANINDAS PROTECTOR 80X180cm ADJ B25 | BAG |
| 18410520039159 | 1834015 | SABANINDAS PROTECTOR 80X180cm ADJ C150 | BOX |
| 8410520033686 | 1834020 | SABANINDAS NORMAL PROTECTOR 60X90cm B12 | BAG |
| 18410520033683 | 1834020 | SABANINDAS NORMAL PROTECTOR 60X90cm C72 | BOX |
| 18410520056033 | 2834009 | SABANINDAS PROTECTOR NORMAL 60X60cm (M) 40B1 | BOX |
| 18410520056040 | 2834010 | SABANINDAS PROTECTOR NORMAL 60X90cm (M) 40B1 | BOX |
| 18410520006991 | 2834018 | SABANINDAS PROTECTOR EXTRA 60X40cm (M) 40B1 | BOX |
| 18410520054985 | 2834019 | SABANINDAS PROTECTOR EXTRA 60X60cm (M) 40B1 | BOX |
| 8410520039107 | 2834021 | SABANINDAS PROTECTOR EXTRA 60X40cm B25 | BAG |
| 28410520039101 | 2834021 | SABANINDAS PROTECTOR EXTRA 60X40cm C200 | BOX |
| 8410520039114 | 2834023 | SABANINDAS PROTECTOR EXTRA 60X60cm B20 | BAG |
| 28410520039118 | 2834023 | SABANINDAS PROTECTOR EXTRA 60X60cm C120 | BOX |
| 8410520039121 | 2834025 | SABANINDAS PROTECTOR EXTRA 60X75cm B20 | BAG |
| 28410520039125 | 2834025 | SABANINDAS PROTECTOR EXTRA 60X75cm C120 | BOX |
| 8410520039138 | 2834027 | SABANINDAS PROTECTOR EXTRA 60X90cm B20 | BAG |
| 28410520039132 | 2834027 | SABANINDAS PROTECTOR EXTRA 60X90cm C120 | BOX |
| 8410520039268 | 2834029 | SABANINDAS PROT EXTRA 80X180cm ADJ B20 | BAG |
| 28410520039262 | 2834029 | SABANINDAS PROT EXTRA 80X180cm ADJ C120 | BOX |
| 18410520022366 | 2834085 | SABANINDAS PROTECTOR EXTRA 60X75cm (M) 40B1 | BOX |
| 18410520006359 | 2834087 | SABANINDAS PROTECTOR EXTRA 60X90cm (M) 40B1 | BOX |
| 18410520006342 | 2834089 | SABANINDAS PROT EXTRA 80X180cm ADJ (M) 40B1 | BOX |
| 8410520009179 | 3805523 | INDASBED PROTECTOR 60X60cm B20 | BAG |
| 18410520009176 | 3805523 | INDASBED PROTECTOR 60X60cm C120 | BOX |
| 8410520033709 | 3805527 | INDASBED PROTECTOR 60X90cm B20 | BAG |
| 18410520033706 | 3805527 | INDASBED PROTECTOR 60X90cm C120 | BOX |
| 8410520043111 | 3805532 | INDASBED BASIC PROTECTOR 60X90cm B20 | BAG |
| 18410520043118 | 3805532 | INDASBED BASIC PROTECTOR 60X90cm C120 | BOX |
| 8410520043111 | 3805533 | INDASBED BASIC PROTECTOR 60X90cm B20 | BAG |
| 38410520043112 | 3805533 | INDASBED BASIC PROTECTOR 60X90cm C120 | BOX |



BASIC UDI: 5601009PAI9T

| UDI | REF | DESCRIPCIÓN | LOGISTICS PACKAGE |
|----------------|------------|------------------------------------|--------------------------|
| 5601009973217 | 3866796 | PINGO DOCE PROTECTOR 80X180cm B20 | BAG |
| 15601009973214 | 3866796 | PINGO DOCE PROTECTOR 80X180cm C120 | BOX |

BASIC UDI: 8480000PADC

| UDI | REF | DESCRIPCIÓN | LOGISTICS PACKAGE |
|----------------|------------|-----------------------|--------------------------|
| 8480000473776 | 3876130 | DELIPLUS 60X90cm B20 | BAG |
| 38480000473777 | 3876130 | DELIPLUS 60X90cm C120 | BOX |