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| Record | | |
| OC-000784-RC | EU Declaration of Conformity - ASISU® | Revision: Issue 1 |

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|--|---|
| Legal Manufacturer | oasicare ApS |
| EU Product Classification according to Annex VIII | I (Rule 5 and Rule 4) |
| Intended purpose | This medical device is intended to protect the perineum during the second stage of vaginal childbirth. It is intended to be used by qualified midwives, obstetric clinicians and other professional birth attendants, in clinical and community-birth environments, to reduce the risk of perineal tears and associated adverse consequences. |
| Basic UDI-DI | 574600000530ASISUJV |
| Conformity Assessment Procedure | Manufacturer self-declaration |
| Notified Body Name and Number | N/A |
| Notified Body Certificate Type and Number | N/A |
| Conformity to Common Specification(s) | No relevant common specification to list |
| Conformity to other Union Legislation(s) | No relevant Union legislation to list |

This EU Declaration of Conformity is applicable for the following catalogue number:

| Catalogue Number | Product Name | Original CE Marking date (DD/MM/YYYY) |
|-------------------------|---------------------|--|
| ASISU-01 | ASISU® | 14/04/2026 |

This EU Declaration of Conformity is issued under the sole responsibility of oasicare ApS. oasicare ApS declares that the device covered by the present declaration is in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled.

| Date of signature (DD/MM/YYYY) | Place of Signature (Place, Country) | Signed on behalf of oasicare ApS (Name, Title) | Signature |
|---|--|---|--|
| 14/04/2026 | Copenhagen, Denmark | Ditte Marie Fog Ibsen, CEO | DocuSigned by:  30AC2BB6B1594A4... |

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Approved version: 1

Title: EU Declaration of Conformity - ASISU®

Approved By:

CEO - Ditte Marie Fog Ibsen Tue Apr 14 10:05:33 GMT 2026

Signed y3fkYVo/twr1F3RufRqlzSyXNM8

Approval History:

| Change Comment | Approved on | Status | Issued by |
|--------------------|-----------------|----------|---------------------|
| Initial CE marking | Tue Apr 14 2026 | Approved | Abeer Prakash Singh |
| Change Comment | Approved on | Status | Issued by |