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oasicare

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

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: Ditte Marie Fog Ibsen 30AC2BB6B1594A4...

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Document: OC-000784-RC

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**