



Medicines & Healthcare products Regulatory Agency

> 10 South Colonnade Canary Wharf London E14 4PU United Kingdom

> > gov.uk/mhra

Amstermed UK Ltd Unit 109 - 54 Bloomfied Avenue Belfast BT5 5AD Northern Ireland, United Kingdom

11 April 2023

Dear Natalie McRoberts

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **05 April 2023** has been reviewed:

Application reference: 2023040501301627

Manufacturer organisation: Cephas Medical Pvt Ltd

Address:

Plot B-21, Phase-I, MEPZ-SEZ-Tambaram Tamil Nadu Kanchipuram 600045 India

Manufacturer registration status: Registered

Device(s):

GMDN Code & Term	Status	Comment
34929 - Urinary incontinence penis sheath/port, single-use	Registered	

Please note this letter does not represent any form of <u>accreditation</u>, <u>certification or approval</u> by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

- 1. company/organisation information e.g. name and address
- 2. additional devices (GMDN code or term)

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our <u>Public Access Registration Database</u> (PARD). In vitro diagnostic medical devices registered as undergoing performance evaluation study are not published on this database.

The account number for your company/organisation is **0000028427**.

Please do not respond directly to this email address. The originating email account is not monitored.

Yours sincerely,

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Device registrations service

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Devices division

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