Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Medical Devices Program

Internal Form

Application Information

Application ID:	DV-2024-CR-23983-1
Submission ID:	**DR-2024-07878-1**
TRIM folder:	E24-373152

Sponsor:	The Global Beauty Group s22 [redacted] s22 s47, s47G [redacted]
ARTG Number(s):	295158
Classification:	Class IIb
Product name:	Intense pulsed light skin surface treatment system
Manufacturer's name (in the ARTG entry):	Shandong Huamei Technology Co Ltd
Manufacturer's address (in ARTG entry):	588 Changning Street High-tech District Weifang Shandong 261205 China
Manufacturer's evidence Id:	**Manufacturer Certificate Id:** DV-2017-MC-12943-1 **Notified Body:** **Notified Body Certificate:** G1 096896 0002 Rev. 03 **Certification type:** Council Directive 93/42/EEC (MDD) **Annex route:** Schedule 3 Part 1 (Annex II) **Expiry Date:** 26/05/2024

GMDN Term & Code:	58935 Intense pulsed light skin surface treatment system
Intended purpose:	The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; and Hirsutism.
Original File:	DV-2017-DA-14115-1
Specific Conditions of entry:	-

Reason for the request

Intended Purpose	
Are you varying the intended purpose?	● Yes ○ No
Existing intended purpose:	The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; and Hirsutism.
New intended purpose:	s47G [redacted] Correction under section 9D to amend purpose entered on ARTG to include: Treatment of ACNE. Acne was included on the ARTG entry this entry superseded and was supposed to be included on this entry but was overlooked. There is representative information available from the time of inclusion to demonstrate that treatment of acne should have been included on the ARTG as part of the intended purpose. Current intended purpose: The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; and Hirsutism. Proposed intended purpose: The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; Hirsutism; Acne.
Is there any change in scope to the intended purpose?	○ Yes, reduction in scope ● Yes, expansion in scope ○ No change

Assessment

Assessor comments

Request 1. **Change the Intended Purpose** **Expansion in scope**	From: The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; and Hirsutism. To: The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; Hirsutism; Acne.
GMDN	58935: Intense pulsed light skin surface treatment system – TGA code table A mains electricity (AC-powered) mobile (on wheels) device designed to produce strong, controlled flashes of filtered light in the wavelength range 560 - 1200nm [intense pulsed light (IPL)] to cause heat ablation of pigmented skin cells (selective photothermolysis) to treat a variety of skin/pigmentation conditions. The device typically enables variation of treatment parameters (wavelength, duration of impulses, single/multiple impulses) for treatment of conditions such as acne, telangiectasia, pigmentation (freckles, sun spots, liver spots) and/or for hair reduction. It consists of a control unit with user interface display and control panel, and a wire-connected applicator. 58935: Intense pulsed light skin surface treatment system – GMDN agency A mains electricity (AC-powered) mobile (on wheels) device designed to produce strong, controlled flashes of filtered light in the wavelength range 400 - 1200nm [intense pulsed light (IPL)] for heat ablation of pigmented skin cells (selective photothermolysis) to treat multiple skin/pigmentation conditions. The device typically enables variation of treatment parameters (wavelength, duration of impulses, single/multiple impulses) for treatment of conditions such as acne, telangiectasia, pigmentation (freckles, sun spots, liver spots) and/or for hair reduction. It consists of a control unit with user interface display and control panel, and a wire-connected applicator.
	• The proposed IP has scope expansion by using the device for Acne treatment.

	• The proposed Intended Purpose is still covered in both the GMDN agency and TGA code table. • D24-3856569 Sponsor has been sent notification to hold valid CA certificate as the current certificate attached to ME DV-2017-MC-12943-1 is expired. Acceptable to: **Update the Intended Purpose:** **From:** The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; and Hirsutism. **To:** The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; Hirsutism; Acne.

Application Recommendation

Approved

Assessor	s22 [redacted]		
Signature	*Signed electronically in TRIM*	Date	6/09/2024

***Delegate's Decision*: Approve**

Comments:

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 9D of the *Therapeutic Goods Act 1989* (the Act), I have decided to vary the Australian Register of Therapeutic Goods (ARTG) under subsection 9D(3D) of the Act following your request on the basis that the information provided for this variation does not indicate any reduction in the quality, safety or performance of the kinds of medical devices for the purposes for which these devices are intended to be used.

Changes to be made to the ARTG:

9D Admin:

1. **Update the Intended Purpose:**

From:

The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; and Hirsutism.

To:

The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; Hirsutism; Acne.

Delegate	s22 [redacted]		
Signature	*Signed electronically in TRIM*	Date	11/09/2024

Version History

Version	TRIM Reference	Description of change	Authors	Effective date
V1.0	D23-5360300	New form	s22 [redacted]	17 May 2023
V2.0	D24-2907884	Updated to new template. Terminology updated from 'Reject' to 'Refuse' for consistency with legislation.	s22 [redacted]	16 July 2024

s22 [redacted]

From: s22 [redacted]
Sent: Friday, 6 September 2024 11:54 AM
To: s22 [redacted] s47, s47G
Subject: Device Change Request - Application ID - DV-2024-CR-23983-1, ARTG 295158 [SEC=OFFICIAL]

Dear s22 [redacted]

Application number	ARTG	Classification	GMDN code
DV-2024-CR-23983-1	295158	Class IIb	58935 Intense pulsed light skin surface treatment system

Thank you for your DCR to change the Intended Purpose. Upon review it has been identified that the **MDD certificate no. G1 096896 0002 Rev. 03** held by the manufacturer evidence (ME) DV-2017-MC-12943-1 linked to ARTG 295158 issued to Shandong Huamei Technology Co Ltd was expired on 26 May 2024.

Please ensure that you hold an updated conformity assessment (CA) certificate that covers the device included in ARTG 295158. It is a sponsor's responsibility to hold a valid ME that covers the device included in their ARTG entry and be able to provide it to the TGA upon request. To keep your ARTG entry up to date and accurate, you are also encouraged to submit a variation to the ME DV-2017-MC-12943-1 with the updated CA certificate.

Please let us know if you have any questions.

Kind regards

s22 [redacted]
Medical Devices Assessor

Devices Application and Triage Section | Medical Devices Authorisation Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s22 [redacted], Email: s22 [redacted] @Health.gov.au

PO Box 100, Woden ACT 2606
www.tga.gov.au

Device Change Request

Application ID:	DV-2024-CR-23983-1
Status:	Under Review
Date Received:	19/08/2024

Change history

E24-373152 (s22 , 22/08/2024)

Review Information

Review flag:	
Auto review required:	No

Sponsor Details

Agent Name:	
Applicant Address:	s47, s47G
Sponsor Name:	The Global Beauty Group
Contact Name:	s22
Email Address:	s22 s47, s47G
Phone Number:	s22

Change Request

ARTG No:	295158
ChangeType:	Variation to ARTG Included Entry (Medical Devices and IVDs)
Are you making the same change across multiple ARTG entries:	○ Yes ● No
EU MDR or EU IVDR/MDSAP (IVDs only)	
Are you changing to an EU MDR or EU IVDR/MDSAP (IVDs only) certification?	○ Yes ● No
Manufacturer Evidence	
Are you changing manufacturer details (i.e. name and/or address)?	○ Name ○ Address ○ Both ● Neither
Are you seeking to link your ARTG entries to a new approved notification of Manufacturer Evidence	○ Yes ● No

(ME)?

Intended Purpose	
Are you varying the intended purpose?	● Yes ○ No
Existing intended purpose:	The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; and Hirsutism.
New intended purpose:	s47G [redacted]. Correction under section 9D to amend purpose entered on ARTG to include: Treatment of ACNE. Acne was included on the ARTG entry this entry superseded and was supposed to be included on this entry but was overlooked. There is representative information available from the time of inclusion to demonstrate that treatment of acne should have been included on the ARTG as part of the intended purpose. Current intended purpose: The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; and Hirsutism. Proposed intended purpose: The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; Hirsutism; Acne.
Is there any change in scope to the intended purpose?	○ Yes, reduction in scope ● Yes, expansion in scope ○ No change
GMDN Code and Description	
Are you varying the GMDN code and description?	○ Yes ● No
Other Changes	
Are there any other changes you are seeking which have not been identified above?	○ Yes ● No
TGA identifiers for recently submitted DCR or Variation applications covering similar changes to other medical devices:	
Attachments:	Declaration of Conformity - AU Declaration of Conformity-IPLinclAcne.pdf
Description:	

Payment Details

Fee	$1047.00

Shandong Huamei Technology Co.,Ltd.
Add: 588, Changning Street, High-tech District, Weifang, Shandong 261205 People's Republic of China
Tel: +86 536 2110005; 2110008; 2110001
Fax: +86 536 2109823

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURE

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian ***Therapeutic Goods (Medical Devices) Regulations 2002*** relating to the stated devices

Manufacturer's Name:	***Shandong Huamei Technology Co., Ltd.***
Business Address:	***588, Changning Street, High-tech District, Weifang, Shandong 261205 People's Republic of China***
Medical Device(s):	***Medical Intense Pulsed Light Treatment System***
	HM-IPL-B1, HM-IPL-B3, HM-IPL-B6, HM-IPL-B8, EROSE-Y, EROSE-YA
Classification:	***IIb, Rule 9***
GMDN Code and Term:	***58935***
Intended purpose:	***The Intense Pulsed Light Treatment System is intended to clinically treat Pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; acne and Hirsutism.***
Scope of Application:	***Specific (HM-IPL-B1, HM-IPL-B3, HM-IPL-B6, HM-IPL-B8, EROSE-Y, EROSE-YA)***

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Full Quality Management System Certificate: European Medical Devices Directive Annex II without Clause 4 Certificate(s)

Assessment Body and Certificate Number: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany G1 096896 0002 Rev.03

Certificate issue date: 2024-05-27

Certificate expiry date: 2028-12-31

Standards Applied: ***EN ISO 15223-1：2016, EN 1041:2008, EN ISO 14971:2019, IEC 60601-1:2006+AC:2010+A1:2013+A12:2014, IEC 60601-1-2:2015, IEC 60601-2-57:2011, EN 62366:2015, EN 62304:2015, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010.***

Authorised Signatory:

Name, Position

SHANDONG HUAMEI TECHNOLOGY CO.,LTD. 山东美科技有限公司

2024.8.15

Date

s22 [redacted]

From: s22 [redacted]
Sent: Tuesday, 10 September 2024 9:27 AM
To: s22 [redacted] s47, s47G
Subject: TGA Application - DR-2024-07878-1 - DV-2024-CR-23983-1 - The Global Beauty Group - Pushback [SEC=OFFICIAL]

Dear s22 [redacted]

I have pushed back your application for you to amend the **Proposed Intended Purpose.** Please remove additional sentences including the current intended purpose from the proposed intended purpose field. Only the proposed intended purpose should remain. Otherwise, everything in there will be copied to the ARTG certificate as the intended purpose after approval of the DCR. If you'd like to keep that additional info in your application form, you can provide that in the 'Other changes' (free text field).

The pushed back application will appear in the "Portal" area - "View Drafts" section in the TGA eBusiness Services (https://www.ebs.tga.gov.au) and is identified by the status of "Review Requested".

1. To amend/correct the application, click on the relevant link under the identifier column or the "sponsors own reference" column.
2. When you click on the relevant application it will automatically open the application form.
3. You can now amend/correct the application. Please ensure that the "Declaration" is signed by indicating "Yes" to the conditions of the declaration and then revalidate the application using the "validate" button.
4. A "validation successful" indicator will be generated in the left corner.
5. When this is complete, please click on the "Continue" or "Submit" button and the device application will then be submitted to the TGA.

If you are having any difficulties with editing the application, please contact the TBS Helpdesk - ebs@health.gov.au.

PLEASE DO NOT DELETE THE APPLICATION.

Please notify me when you have resubmitted the application for further review.

Please complete this task and resubmit by close of business 13 September 2024

Kind regards,

s22 [redacted]
Medical Devices Assessor

Devices Application and Triage Section | Medical Devices Authorisation Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location Fairbairn
Phone: s22 [redacted], Email: s22 [redacted] @Health.gov.au

PO Box 100, Woden ACT 2606
www.tga.gov.au

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

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From: s22 s47, s47G
To: s22
Subject: RE: TGA Application - DR-2024-07878-1 - DV-2024-CR-23983-1 - The Global Beauty Group - Pushback [SEC=OFFICIAL]
Date: Tuesday, 10 September 2024 11:19:50 PM
Attachments: image002.png
image003.png
image004.png
image005.png
image006.png
image007.png

Dear s22

The application has been re-submitted per your instructions.

Kindest regards,
s22

s22
s22
s47, s47G

- s22
- s22 s47, s47G
- s47, s47G
- s47, s47G

s47, s47G

From: s22 @Health.gov.au>
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s22 [redacted]
Medical Devices Assessor

Devices Application and Triage Section | Medical Devices Authorisation Branch
Australian Government, Department of Health and Aged Care
Therapeutic Goods Administration

Location
Phone: s22 [redacted], Email: s22 [redacted] @Health.gov.au

PO Box 100, Woden ACT 2606
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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

The Global Beauty Group

for approval to supply

The Global Beauty Group - Intense pulsed light skin surface treatment system

ARTG Identifier	295158
ARTG Start Date	16/10/2017
Product Category	Medical Device Included Class IIb
GMDN	58935
GMDN Term	Intense pulsed light skin surface treatment system
Intended Purpose	The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; and Hirsutism.

Manufacturer Details	Address	Certificate number(s)
Shandong Huamei Technology Co Ltd	588 Changning Street High-tech District Weifang , Shandong , 261205 China	DV-2017-MC-12943-1

ARTG Standard Conditions

The above Medical Device Included Class IIb has been entered on the Register subject to the following conditions:

· - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Intense pulsed light skin surface treatment system

Product Specific Conditions

· No specific conditions have been recorded against this entry.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

The Global Beauty Group

for approval to supply

The Global Beauty Group - Intense pulsed light skin surface treatment system

ARTG Identifier	295158
ARTG Start Date	16/10/2017
Product Category	Medical Device Included Class IIb
GMDN	58935
GMDN Term	Intense pulsed light skin surface treatment system
Intended Purpose	The Intense Pulsed Light Treatment System is intended to clinically treat pigmentary changes, including pigmentary lesions and other conditions brought about by sun damage and photoaging; Vascular changes, including telangiectasias, rosacea; Hirsutism; Acne.

Manufacturer Details	Address	Certificate number(s)
Shandong Huamei Technology Co Ltd	588 Changning Street High-tech District Weifang , Shandong , 261 205 China	DV-2017-MC-12943-1

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Products Covered by This Entry

1. Intense pulsed light skin surface treatment system

Product Specific Conditions

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