

NOTICE OF FILING AND HEARING

Filing and Hearing Details

Document Lodged:	Originating Application - Form 15 - Rule 8.01(1)
Court of Filing:	FEDERAL COURT OF AUSTRALIA (FCA)
Date of Lodgment:	2/06/2025 2:17:45 PM AEST
Date Accepted for Filing:	3/06/2025 9:49:05 AM AEST
File Number:	NSD867/2025
File Title:	SECRETARY OF THE DEPARTMENT OF HEALTH, DISABILITY AND AGEING v PHILIPS ELECTRONICS AUSTRALIA LIMITED ACN 008 445 743
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA
Reason for Listing:	To Be Advised
Time and date for hearing:	To Be Advised
Place:	To Be Advised



Sia Lagos

Registrar

Important Information

This Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

The date of the filing of the document is determined pursuant to the Court's Rules.



Originating application

No. of 20

Federal Court of Australia
District Registry: New South Wales
Division: General

Secretary of the Department of Health, Disability and Ageing

Applicant

Philips Electronics Australia Limited ACN 008 445 743

Respondent

To the Respondent

The Applicant applies for the relief set out in this application.

The Court will hear this application, or make orders for the conduct of the proceeding, at the time and place stated below. If you or your lawyer do not attend, then the Court may make orders in your absence.

You must file a notice of address for service (Form 10) in the Registry before attending Court or taking any other steps in the proceeding.

Time and date for hearing: [Registry will insert time and date]

Place: [address of Court]

The Court ordered that the time for serving this application be abridged to [Registry will insert date, if applicable].

Filed on behalf of (name & role of party)	Secretary of the Department of Health, Disability and Ageing, Applicant		
Prepared by (name of person/lawyer)	Rebecca Jaffe		
Law firm (if applicable)	HWL Ebsworth Lawyers		
Tel	(03) 8644 3500	Fax	1300 365 323
Email	rjaffe@hwle.com.au		
Address for service (include state and postcode)	Level 8, 447 Collins Street, MELBOURNE 3000		

[Version 2 form approved 09/05/2013]



Date:

Signed by an officer acting with the authority
of the District Registrar



Details of claim

On the grounds stated in the Concise Statement, the Applicant claims:

1. Declarations pursuant to s 21 of the *Federal Court of Australia Act 1976* (Cth) that:
 - a. During the period 2 June 2019 to 2 June 2021, on each occasion that the respondent, being the person in relation to whom a kind of medical device (**Device**) listed in the Schedule below was included in the Australian Register of Therapeutic Goods (**ARTG**), supplied a Device containing polyester-based polyurethane foam:
 - i. the Device did not comply with essential principles 1, 2, 3, 4, 7.1(a), 7.6 and/or 9.2 in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) (**Regulations**);
 - ii. the Applicant did not consent to the supply of the Device for the purposes of s 41MAA(2)(c) of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**);
 - iii. for the purposes of s 41MAA(2)(d) of the TG Act, the Device was not covered by an exemption in force under s 41GS; and
 - iv. by reason of (i) to (iii) above, the respondent contravened s 41MAA(2) of the TG Act.
 - b. During the period 7 July 2021 to 13 October 2022, on each occasion that the respondent supplied the Trilogy 100 Device, being a model of a Device listed in the Schedule under ARTG 159490, with silicone sound abatement foam:
 - i. the Trilogy 100 Device did not comply with essential principles 1, 2, 3, 4, and/or 6 in Schedule 1 of the Regulations;
 - ii. the Applicant did not consent to the supply of such Trilogy 100 Device for the purposes of s 41MAA(2)(c) of the TG Act;
 - iii. for the purposes of s 41MAA(2)(d) of the TG Act, the Trilogy 100 Device was not covered by an exemption in force under s 41GS; and
 - iv. by reason of (i) to (iii) above, the respondent contravened s 41MAA(2) of the TG Act.
2. An order pursuant to s 42Y(2) of the TG Act that within 30 days of the date of this order the respondent pay to the Commonwealth of Australia such pecuniary penalties as the Court determines to be appropriate in respect of each contravention pleaded in the Concise Statement and declared by the Court.
3. Costs.
4. Such further or other orders as the Court considers appropriate.



Schedule: Devices

ARTG ID	Model	Product Code
159490	Trilogy 100	AU1054096B
200289	BiPAP A40 (A-Series)	1111171
209934	DreamStation BiPAP ASV	AUX900T15
		AUX900T15C
285420	DreamStation AVAPS/ST Ventilator	AUX1131T15
327227	OmniLab Advanced +	1111127
295664	DreamStation CPAP	AUX400S15
		AUX400T15
		AUX400T15C
	DreamStation Auto CPAP	AUX500S15
		AUX500T15
		AUX500T15C
	REMstar Pro System One 60 Series	AU461TS
	REMstar Auto System One 60 Series	AU561S
		AU561TS
257012	DreamStation Auto BiPAP	AUX700T15
		AUX700T15C
257013	DreamStation Go	AUG400S15
		AUG500S15
		AUG400H15
		AUG500H15

Applicant's address

The Applicant's address for service is:

Place: Level 8, 447 Collins Street, MELBOURNE 3000

Email: rjaffe@hwle.com.au

The Applicant's address is:

HWL Ebsworth Lawyers,

Level 8, 447 Collins Street | Melbourne VIC 3000



Service on the Respondent

It is intended to serve this application on all Respondents.

Date 2 June 2025

A handwritten signature in blue ink, appearing to be "Rebecca Jaffe", is written above a horizontal dotted line.

Signed by Rebecca Jaffe
Lawyer for the Applicant