



## **Therapeutic Goods (Biologicals—Specified Things) Instrument 2021**

---

I, John Skerritt, as delegate of the Secretary of the Department of Health, make the following instrument.

Dated 24 September 2021

Adjunct Professor John Skerritt  
Deputy Secretary  
Health Products Regulation Group  
Department of Health

---



---

## Contents

1 Name.....	1
2 Commencement .....	1
3 Authority.....	1
4 Definitions .....	1
5 Specified things—biologicals .....	2
6 Specified things—not biologicals .....	2
7 Repeals.....	2
<b>Schedule 1—Specified things: biologicals</b>	<b>3</b>
<b>Schedule 2—Specified things: not biologicals</b>	<b>4</b>
<b>Schedule 3—Repeals</b>	<b>5</b>
<i>Therapeutic Goods (Things that are Biologicals) Specification 2019</i>	5
Therapeutic Goods (Things that are not Biologicals) Determination No.1 of 2011	5



---

## 1 Name

This instrument is the *Therapeutic Goods (Biologicals—Specified Things) Instrument 2021*.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	30 September 2021.	30 September 2021

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under section 32A of the *Therapeutic Goods Act 1989*.

## 4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:  
(a) biological.

In this instrument:

*Act* means the *Therapeutic Goods Act 1989*.

*biological medicine* has the same meaning as in the Regulations.

*faecal microbiota transplant product* has the same meaning as in the Regulations.

*in-house IVD medical device* has the same meaning as in the Medical Devices Regulations.

*IVD medical device* has the same meaning as in the Medical Devices Regulations.

*Medical Devices Regulations* means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

---

*Regulations* means the *Therapeutic Goods Regulations 1990*.

## **5 Specified things—biologicals**

For subsection 32A(2) of the Act, the things mentioned in Schedule 1 are specified for the purposes of subparagraph 32A(1)(a)(ii) of the Act.

## **6 Specified things—not biologicals**

For subsection 32A(3) of the Act, the things specified in Schedule 2 are determined not to be biologicals for the purposes of the Act.

## **7 Repeals**

Each instrument that is specified in Schedule 3 is repealed as set out in the applicable items in that Schedule.

---

## Schedule 1—Specified things: biologicals

Note: See section 5.

---

Specified things for the purposes of subparagraph 32A(1)(a)(ii) of the Act	
Column 1	Column 2
Item	Specified things
1	a thing that comprises or contains live animal cells, tissues, or organs
2	a thing that is a faecal microbiota transplant product

---

---

## Schedule 2—Specified things: not biologicals

Note: See section 6.

---

<b>Specified things that are not biologicals</b>	
<b>Column 1</b>	<b>Column 2</b>
<b>Item</b>	<b>Specified things</b>
1	biological medicines, other than vaccines that contain viable human cells
2	haematopoietic progenitor cells used for haematopoietic reconstitution
3	IVD medical devices and in-house IVD medical devices
4	samples of human cell or tissue of an individual that are solely for diagnostic purposes in that individual

---

Note: Biological medicines include blood and blood components.



---

## **Schedule 3—Repeals**

Note: See section 7.

### ***Therapeutic Goods (Things that are Biologicals) Specification 2019***

#### **1 The whole of the instrument**

Repeal the instrument.

### **Therapeutic Goods (Things that are not Biologicals) Determination No.1 of 2011**

#### **2 The whole of the instrument**

Repeal the instrument.