B Braun Australia Pty Ltd – M.scio Dome Implant (ARTG 485346), M.scio Flat Implant (ARTG 485347), M.scio Flat Implant with Distal Catheter (ARTG 485886) and M.scio Dome Implant with Distal Catheter

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by B Braun Australia Pty Ltd

I, Michael Shum, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from B Braun Australia Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph **(A)**, for use in advertisements for the product identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed or communicated[1] in the advertisement in which the restricted representations are used (including on the label and packaging of the goods).

(A)

- *M.scio Flat (provided with or without catheter) is intended for use in the treatment of patients with hydrocephalus (including subarachnoid haemorrhage induced hydrocephalus) by measuring intracranial pressure.*
- *M.scio Dome (provided with or without catheter) is intended for use in the treatment of patient with hydrocephalus (including subarachnoid haemorrhage induced hydrocephalus) by measuring intracranial pressure, enabling hypodermic infusion or injection of therapeutic substances, and facilitating cerebrospinal fluid drainage.*

(B)

- M.scio Dome Implant (ARTG 485346)
- M.scio Flat Implant (ARTG 485347)
- M.scio Flat Implant with Distal Catheter (ARTG 485886)
- M.scio Dome Implant with Distal Catheter (ARTG 485885)

[1] ***prominently displayed or communicated***, in relation to a statement in an advertisement, means:
(a) either:
(i) for a visual statement—easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or
(ii) for a spoken statement—able to be clearly heard and understood; and
(b) repeated as often as necessary to be noticed by a viewer or listener

(C)

- **Important Safety Information**

The information provided is intended solely for educational purposes and should not be considered a substitute for professional medical advice. Always consult your doctor or qualified healthcare professional for guidance regarding your health or treatment options. Please consult your doctor or neurosurgeon to determine whether M.scio implant therapy is appropriate for your condition. Only a qualified medical professional can assess and decide which treatments and devices are suitable for your individual needs. As with any surgical procedure, implantation of an M.scio implant carries certain risks. Your surgeon will explain all potential complications, as well as any possible side effects associated with the procedure.

- **Risk Associated with M.scio**

Measuring intracranial pressure with the M.scio and treating hydrocephalus with a shunt system is not always without complications. As with every surgical intervention, there is a risk of infection. Unfortunately, problems can occasionally develop that could be directly or indirectly linked to the implanted shunt system. Such complications include: Headache, dizzy spells, mental confusion, vomiting in cases of potential leakage from the M.scio/shunt and shunt dysfunction, Redness/irritation of the skin and tightness around the implantation site as an indication of a possible infection at the implant, Blockages due to protein and/or blood in the cerebrospinal fluid, Wound healing disorders because of the height of the dome-angled M.scio. A physician must be consulted immediately in case of skin rashes and tightness, severe headaches, dizzy spells or similar.

The following residual risks are possible with the use of the M.scio:

- Persistent headache
- Severe infection (e.g. sepsis, meningitis)/allergic shock
- Acute hygroma / subdural haematoma (SDH)
- Cerebrospinal fluid accumulations (cerebrospinal fluid under the skin)
- Tissue damage/puncture
- Chronic hygroma
- Skin irritation
- Local shunt irritation/allergic reaction

- **Contraindications**

M.scio is not indicated:

1. If there is risk of post-operative bleeding
2. If there is blood in CSF
3. For infections or a suspected infection in the regions of the body affected by implantation
4. For aggressive and auto -aggressive patient behaviours
5. Expected high pressure and shock loads

Determining whether a patient is an appropriate candidate for treatment with M.scio requires the expertise of a qualified surgeon. M.scio is not universally suitable for all individuals diagnosed with hydrocephalus. Patient selection must be based on a thorough assessment, clinical history, and diagnostic imaging. It is essential that patients consult with their neurologist to evaluate whether M.scio is an appropriate therapeutic option for their specific condition.

Dated this 19th day of January 26

Signed electronically
Michael Shum
Delegate of the Secretary to the Department of Health, Disability and Ageing
Education Policy and Guidance Section
Regulatory Compliance Branch