

DECLARATION OF CONFORMITY

According to the Council Directive 2001/95/EC, on General Product Safety,

We, Myospots Australia Pty Ltd of 33 Hutchinson street, Burleigh Heads, 4220, QLD, Australia, declare under our sole responsibility that the following Products meet the provisions of the Council Directive 2001/95/EC which apply to them:

Myospots Tongue Exercise Spots

The products are intended to be used as **Tongue Exerciser**

Myospots are small, solid, circular dissolvable discs of ~6 mm diameter and ~3 mm thickness. Myospots are used for the exercise of tongue muscles and to train the tongue to elevate and rest on the palate (roof of the mouth). These dissolvable discs have strong adhesive properties and slow rate of dissolution. The user places the adhesive spot on the palate, while applying gentle force with his/her thumb. The spot adheres quickly (in a few seconds) to the palate, and the user's tongue becomes stimulated to elevate and touch the adhered spot. The frequent movement and force exerted by the tongue towards the adhered spot helps in exercising tongue muscles and increasing muscle tone. The spot slowly dissolves in saliva under the effect of tongue movement (complete dissolution takes about 45 minutes). The exercise protocol involves repeating this cycle for 2-3 times a day for 2-3 months to increase tongue muscle strength and train the tongue to elevate and rest on the palate.

Conformity assessment was performed according to Chapter II "general safety requirements" The following standards were used to prove the products conformity with the general safety requirements of the above directive:

European GMP (good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention /Co-operation Scheme (PIC/S) and the Directives of the European Commission)

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

Obelis s.a.

Registered Address:

53 Bd. Général Wahis 53

B-1030 Brussels, Belgium

Phone: 32.2.732.60.03

Fax: 32.2.732.60.03

E-mail: mail@obelis.net

Representative: Mr. Gideon ELKAYAM

Gold Coast, Australia, 18/08/2021



Dr Ibrahim El-Deeb
Director

