

QUALITY SYSTEM

EC-CERTIFICATE

Directive 98/79/EC

Manufacturer: Bome Trivitron Sanayi Ürünleri Dış Ticaret A.Ş.
Ostim OSB Mahallesi, 1250.
Cadde, No:1, Yenimahalle, Ankara
TURKEY

Coverage of Certificate: Design, manufacture and final inspection

Product category: Reagents and reagent products for
diagnosing phenylketonuria

Valid until: 29 April 2025

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 98/79/EC as set out in Annex IV Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex IV in Directive 98/79/EC. Products covered by the certificate are specified in the attachment(s).

Valid from: 25 May 2022


Aliisa Siljander




Riikka Kylväjä

Certificate no. **C-02-1208-798-22**

Notified Body no. 0537:
Eurofins Electric & Electronics Finland Oy
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Attachment 1 to the Certificate number: C-02-1208-798-22

Manufacturer:	Bome Trivitron Sanayi Ürünleri Dış Ticaret A.Ş. Ostim OSB Mahallesi, 1250. Cadde, No:1, Yenimahalle, Ankara TURKEY						
Activity and product category:	Design, manufacture and final inspection of reagents and reagent products for diagnosing phenylketonuria GMDN-code: 58960						
Products:	<p>The certificate covers the following products:</p> <table border="1"> <thead> <tr> <th><i>Name</i></th> <th><i>Brand name</i></th> <th><i>Model</i></th> </tr> </thead> <tbody> <tr> <td>Trimaris Neonatal Phenylalanine kit</td> <td>Trimaris Yenidoğan Fenilalanin Kiti</td> <td>BR071230</td> </tr> </tbody> </table>	<i>Name</i>	<i>Brand name</i>	<i>Model</i>	Trimaris Neonatal Phenylalanine kit	Trimaris Yenidoğan Fenilalanin Kiti	BR071230
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Date:	Valid from: 25 May 2022						
	   Aliisa Siljander Riikka Kylväjä						

Eurofins Electric & Electronics Finland Oy is Notified Body no. 0537 under Council Directive 98/79/EC.

EUROFINS ELECTRIC & ELECTRONICS FINLAND OY

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Business ID FI21741879