

## QUALITY SYSTEM

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**EC-CERTIFICATE**

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## Directive 98/79/EC

Manufacturer: Bome Trivitron Sanayi Ürünleri Dış Ticaret A.Ş.  
Sokullu Mehmet Paşa Mah. 1361. Sokak No:6/A  
Sokullu, Çankaya, Ankara  
TURKEY

Coverage of Certificate: Design, manufacture and final inspection

Product category: Reagents and reagent products for  
diagnosing phenylketonuria

Valid until: 27<sup>th</sup> May 2024

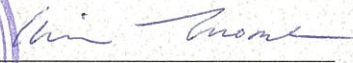
The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 98/79/EC as set out in Annex IV Section 3. This approval is valid until the expiry date provided that the manufacturer 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: 29<sup>th</sup> April 2020



Mikko Soikkeli

Certificate no.  
**C-02-1208-731-20**



Elina Tuomola

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