
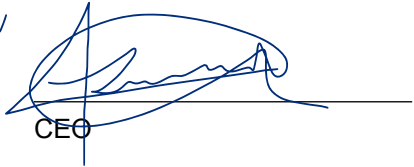


COLORIMETRIX	Pearl by Beurer FSH test strips
Document Title: Declaration of Conformity Pearl by Beurer FSH test strips	
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DECLARATION OF CONFORMITY

Identification of the Legal Manufacturer		Colorimetrix GmbH Michael-Huber-Weg 18 81667, München, Germany		
Identification of Authorized Representative	<table border="1" style="display: inline-table;"><tr><td>EC</td><td>REP</td></tr></table>	EC	REP	N/A
EC	REP			
This Declaration of Conformity is issued under the sole responsibility of the above mentioned Legal Manufacturer				
Unique Device Identifier (UDI) / REF	C-BEUFSSH			
Identification of the device(s) concerned	Pearl by Beurer FSH Test Strips			
Risk Classification	IVDD for self-testing (According to 98/79/EC)			
We hereby declare that the above mentioned devices comply with the Essential Requirements laid down in Annex I and is CE marked in accordance with the European In Vitro Diagnostic Directive 98/79/EC				
Relevant Harmonized Standards	EN ISO 14971 IEC 62304 IEC 62366-1			
Name and address of Notified Body	TÜV SÜD Product Services Ridlerstraße 65 80339 München Germany			
Applicable CE certificate(s)	CE 0123			
Validity of the Declaration of Conformity	Version	1.1		
Identification of the person authorized to sign on behalf of Legal Manufacturer	Name	Dr. Leo Martinez		
	Signature			
	Title	CEO		
	Place of Issue	München		
	Date of Issue	27.04.2020		