Declaration of Conformity	
Manufacturer	Abbott Diagnostics Medical Co., Ltd. 357 Matsuhidai, Matsudo-shi, Chiba 270-2214, JAPAN
Manufacturer SRN No.	JP-MF-000009543
EC Representative	Abbott Rapid Dx International Limited (RDIL) Parkmore East Business Park Ballybrit, Galway, Ireland, H91 VK7E
EC Representative SRN No.	IE-AR-000000091
Basic UDI-DI	457122647HBV00016R
Product and Trade Name	Determine™ HBsAg 2
Catalogue No.	7D2946 / 7D2947
Intended Purpose	Determine™ HBsAg 2 is an in vitro, visually read, rapid qualitative immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human capillary and venous whole blood, plasma or serum. The test is intended as an aid in the diagnosis of Hepatitis B infection in the general population. Determine HBsAg 2 is not intended for use in screening blood, plasma, cell or tissue donors. The test is not automated. Determine™ HBsAg 2 Test Strip is an in vitro diagnostic medical device intended for professional use in a laboratory environment and near-patient testing. It is not intended for self-testing
Risk Class	Class D, Annex VIII Rule 1 & Rule 4(b)
Reference to any Common Specifications	COMMISSION IMPLEMENTING REGULATION (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council
Notified Body	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany
Notified Body No.	0123

Digitally signed by Bolea Petru
Date: 2024.08.18 12:22:53 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Conformity Assessment Route	Annex IX (Regulation (EU) 2017/746)
EC Certificate No.	Full Quality Assurance System: V10 103108 0009 Rev.01 Design Examination: V70 103108 0011 Rev.00

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

I, on behalf of the Manufacturer hereby declare that the device listed above fulfils the requirements specified in Regulation (EU) 2017/746 and is in conformity with this Regulation.

Signature	DocuSigned by Karen Kawada karen kawada この文書を承認する 06-Oct-2023 | 7:03:50 AM CDT 41E29CA6828045CBB1476317...E539815
Name	Karen Kawada
Function	Manager, Regulatory Affairs
Place of Issue	Abbott Diagnostics Medical Co., Ltd.
Date of Issue	06-10-2023