ANHANG I ZUR KONFORMITÄTSERKLÄRUNG
ANNEX I TO DECLARATION OF CONFORMITY

Handelsname Produkt:
Trade name product: **Cube Reader**

Versionen:
Versions: **Flat; Cavity**

Basic UDI-DI: **42520204CUBEDQ**

DIE FOLGENDEN VARIANTEN DES O.G. PRODUKTES SIND IN DER KONFORMITÄTSERKLÄRUNG EINGESCHLOSSEN.
THE FOLLOWING VARIANTS OF THE ABOVE-MENTIONED PRODUCT ARE INCLUDED IN THE DECLARATION OF CONFORMITY.

Hersteller REF **Manufacturer REF**	**UDI-DI**	**Händler** **Distributor**	**Händler Marke / Händler REF** **Distributor brand / Distributor REF**
CUBE-929-01	04252020400025	concile GmbH	concile® α1
CUBE-784-01	04252020400032	nal von minden GmbH	Colibri®
CUBE-241-01	04252020400063	botiss Biomaterials GmbH	botissCARE Cube Reader / VD_Cube
CUBE-941-02	04252020400070	Jungbrunnen - Fountain of Youth GmbH	VHC Reader / VHC-R-001
CUBE-940-03	04252020400087	Affimedix, Inc.	Cube Reader RapiRead™ / RR-101
CUBE-940-04	04252020400094	Unimed, Inc.	Cube Reader QuickREAD™ / QR-555
CUBE-156-01	04252020400100	Bioinova, a.s.	Bi-Reader

Unterschrift:
Signature:

Lutz Melchior
General Manager

.....

Geschäftsführer / Managing Director

Berlin, 2023-12-01

Ort, Datum / Place, date

Name und Funktion bei opTricon GmbH /
Name and function at opTricon GmbH

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

Name und Adresse des Herstellers: Name and address of the Manufacturer:	Chembio Diagnostics GmbH Schwarzschildstr.1 12489 Berlin Germany
SRN des Herstellers (EUDAMED): SRN of the Manufacturer (EUDAMED):	**DE-MF-000024656**

DER HERSTELLER ERKLÄRT HIERMIT, DASS ER DIE ALLEINIGE VERANTWORTUNG FÜR DIE AUSSTELLUNG DER EU-KONFORMITÄTSERKLÄRUNG TRÄGT.

THE MANUFACTURER HEREBY DECLARES THAT HE IS SOLELY RESPONSIBLE FOR ISSUING THE EU DECLARATION OF CONFORMITY.

DER HERSTELLER ERKLÄRT WEITERHIN, DASS DAS IN-VITRO-DIAGNOSTIKUM:
THE MANUFACTURER FURTHER STATES THAT THE IN VITRO DIAGNOSTIC DEVICE:

Handelsname: Trade name:	**Cube Reader**
Versions:	**Flat**; **Cavity**
Basic-UDI-DI:	**42520204CUBEDQ**

MIT DER FOLGENDEN ZWECKBESTIMMUNG:
WITH THE FOLLOWING PURPOSE:

Photometer, bestimmt für die qualitative, halbquantitative oder quantitative Messung der optischen Dichte von Linien auf Teststreifen, die in Lateral-Flow-Assays (LFAs) / Schnelltests für die in-vitro-Diagnostik verwendet werden. Seine Funktion ist insbesondere die Diagnosehilfe im Zusammenhang mit spezifischen LFA-/Reagenzien-Tests, Probenmaterial dieser Tests können jegliche Körperflüssigkeiten und -extrakte sein. Der Nachweis einer Erkrankung, einer Störung oder eines Risikofaktors von Interesse hängt vom durch den Reagenzien-Hersteller definierten Test ab, der diesen mittels RFID-Karte ins Photometer einbringt. Der Reagenzien-Hersteller bestimmt auch die zugehörige Zielpopulation. Die Anwendung findet ausschließlich manuell durch professionelle Anwender statt. Das Photometer selbst ist kein therapiebegleitendes Diagnostikum.

Photometer, intended for the qualitative, semi-quantitative or quantitative measurement of the optical density of lines on test strips used in Lateral Flow Assays (LFAs) / rapid tests for in-vitro diagnostics. In particular, its function is to provide diagnostic assistance in connection with specific LFA tests, sample material for these tests can be any body fluids and extracts. The evidence of a specific disorder, condition, or risk factor of interest depends on the test defined by the manufacturer of the assay reagents, who brings this test into the photometer via use of an RFID card. The manufacturer of the assay reagents also determines the related target population. The application is solely performed manually by professional users. The photometer itself is not a companion diagnostic device.

SOWIE DIE ALS ZUBEHÖR ZUM IVD KLASSIFIZIERTE SOFTWARE:
AS WELL AS THE SOFTWARE CLASSIFIED AS AN ACCESSORY TO THE IVD:

Software name: Software name:	**Cube DataReader Software**
Basic-UDI-DI:	**42520204CUBE-SW4T**

MIT DER FOLGENDEN ZWECKBESTIMMUNG:
WITH THE FOLLOWING PURPOSE:

Softwarezubehör (PC); Nur in Kombination mit Cube Reader zu verwenden; Ermöglicht den Export der Ergebnisdaten vom Reader zum PC und die Steuerung des Readers durch die Software über den PC

Software accessory (PC); Only to be used in combination with Cube Reader; Allows result data export from reader to PC and control of the reader through the software via the PC

WIE FOLGT KLASSIFIZIERT WERDEN NACH VERORDNUNG (EU) 2017/746 ÜBER IN-VITRO-DIAGNOSTIKA (IVDR):
ARE CLASSIFIED AS FOLLOWS ACCORDING TO THE IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (EU) 2017/746 (IVDR):

- ☒ **Klasse A, Anhang VIII, Regel 5 b / Device of Class A, Annex VIII, Rule 5 b**
- ☐ Klasse B, Anhang VIII, Regel … / Device of Class B, Annex VIII, Rule …
- ☐ Klasse C, Anhang VIII, Regel … / Device of Class C, Annex VIII, Rule …
- ☐ Klasse D, Anhang VIII, Regel … / Device of Class D, Annex VIII, Rule …

UND ALLEN ANFORDERUNGEN DER VERORDNUNG ÜBER IN-VITRO-DIAGNOSTIKA (EU) 2017/746 (IVDR) ENTSPRECHEN, DIE ANWENDBAR SIND.

AND COMPLY WITH ALL REQUIREMENTS OF THE IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (EU) 2017/746 (IVDR) THAT APPLY.

Angewandte Gemeinsame Technische Spezifikationen: Applied common technical specifications:	**N/A (bisher keine veröffentlicht / none published yet)**
Konformitätsbewertungsverfahren: Conformity assessment procedure:	**(EU) 2017/746 (IVDR); Art. 17 & Annex II, Annex III**
Konformitätsbewertungsstelle (falls beigezogen): Notified Body (if consulted):	**N/A**

Unterschrift:
Signature:

X

Geschäftsführer / General Manager
Signiert von: Lutz Melchior

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Geschäftsführer / General Manager

Berlin, 2023-12-01

Ort, Datum / Place, date

Name und Funktion bei Chembio Diagnostics GmbH /
Name and function at Chembio Diagnostics GmbH

DÉCLARATION DE CONFORMITÉ / DECLARATION OF CONFORMITY

Nom et adresse du fabricant : Name and address of the Manufacturer:	Chembio Diagnostics GmbH Schwarzschildstr.1 12489 Berlin Germany
SRN du fabricant (EUDAMED) : SRN of the Manufacturer (EUDAMED):	**DE-MF-000024656**

LE FABRICANT DECLARE PAR LA PRESENTE QU'IL EST SEUL RESPONSABLE DE LA DELIVRANCE DE LA DECLARATION UE DE CONFORMITE.

THE MANUFACTURER HEREBY DECLARES THAT HE IS SOLELY RESPONSIBLE FOR ISSUING THE EU DECLARATION OF CONFORMITY.

LE FABRICANT PRECISE EN OUTRE QUE LE DISPOSITIF MEDICAL DE DIAGNOSTIC IN VITRO :
THE MANUFACTURER FURTHER STATES THAT THE IN VITRO DIAGNOSTIC DEVICE:

Nom commercial : Trade name:	**Cube Reader**
Versions:	**Flat**; **Cavity**
Basic-UDI-DI:	**42520204CUBEDQ**

DANS LE BUT SUIVANT :
WITH THE FOLLOWING PURPOSE:

Photomètre destiné à la mesure qualitative, semi-quantitative ou quantitative de la densité optique des raies sur bandelettes réactives utilisées dans les tests à flux latéral (LFA) / tests rapides pour les diagnostics in vitro. Sa fonction est notamment de fournir une aide au diagnostic dans le cadre de tests LFA/réactifs spécifiques ; les échantillons pour ces tests peuvent être tous fluides et extraits corporels. La détection d'une maladie, d'un trouble ou d'un facteur de risque d'intérêt dépend du test défini par le fabricant du réactif, qui l'insère dans le photomètre à l'aide d'une carte RFID. Le fabricant du réactif détermine également la population cible associée. L'application est réalisée exclusivement manuellement par des utilisateurs professionnels. Le photomètre lui-même n'est pas un outil de diagnostic pour accompagner la thérapie.

Photometer, intended for the qualitative, semi-quantitative or quantitative measurement of the optical density of lines on test strips used in Lateral Flow Assays (LFAs) / rapid tests for in-vitro diagnostics. In particular, its function is to provide diagnostic assistance in connection with specific LFA tests, sample material for these tests can be any body fluids and extracts. The evidence of a specific disorder, condition, or risk factor of interest depends on the test defined by the manufacturer of the assay reagents, who brings this test into the photometer via use of an RFID card. The manufacturer of the assay reagents also determines the related target population. The application is solely performed manually by professional users. The photometer itself is not a companion diagnostic device.

AINSI QUE LES LOGICIELS CLASSES ACCESSOIRES DU DIV :
AS WELL AS THE SOFTWARE CLASSIFIED AS AN ACCESSORY TO THE IVD:

Nom du logiciel : Software name:	**Cube DataReader Software**
Basic-UDI-DI:	**42520204CUBE-SW4T**

DANS LE BUT SUIVANT :
WITH THE FOLLOWING PURPOSE:

Accessoires logiciels (PC); À utiliser uniquement en combinaison avec Cube Reader ; Permet l'exportation des données de résultat du lecteur vers le PC et le contrôle du lecteur via le logiciel via le PC

Software accessory (PC); Only to be used in combination with Cube Reader; Allows result data export from reader to PC and control of the reader through the software via the PC

SONT CLASSES COMME SUIT SELON LE REGLEMENT (UE) 2017/746 RELATIF AUX DISPOSITIFS MEDICAUX DE DIAGNOSTIC IN VITRO (IVDR) :

ARE CLASSIFIED AS FOLLOWS ACCORDING TO THE IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (EU) 2017/746 (IVDR):

- ☒ **Classe A, Annexe VIII, Règle 5 b / Device of Class A, Annex VIII, Rule 5 b**
- ☐ Classe B, Annexe VIII, Règle … / Device of Class B, Annex VIII, Rule …
- ☐ Classe C, Annexe VIII, Règle … / Device of Class C, Annex VIII, Rule …
- ☐ Classe D, Annexe VIII, Règle … / Device of Class D, Annex VIII, Rule …

ET SE CONFORMER A TOUTES LES EXIGENCES DU REGLEMENT (UE) 2017/746 SUR LES DISPOSITIFS DE DIAGNOSTIC IN VITRO (IVDR) APPLICABLES.

AND COMPLY WITH ALL REQUIREMENTS OF THE IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (EU) 2017/746 (IVDR) THAT APPLY.

Spécifications techniques communes appliquées : Applied common technical specifications:	**N/A (aucune publiée pour le moment / none published yet)**
Procédure d'évaluation de la conformité : Conformity assessment procedure:	**(EU) 2017/746 (IVDR); Art. 17 & Annex II, Annex III**
Organisme notifié (si consulté) : Notified Body (if consulted):	**N/A**

Signature:

X

Geschäftsführer / General Manager
Signiert von: Lutz Melchior

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Directeur Général / General Manager

Berlin, 2023-12-01

Lieu, date / Place, date

Nom et fonction chez Chembio Diagnostics GmbH /
Name and function at Chembio Diagnostics GmbH

DICHIARAZIONE DI CONFORMITÀ / DECLARATION OF CONFORMITY

Nome e indirizzo del produttore: Name and address of the Manufacturer:	Chembio Diagnostics GmbH Schwarzschildstr.1 12489 Berlin Germany
SRN del produttore (EUDAMED): SRN of the Manufacturer (EUDAMED):	**DE-MF-000024656**

IL PRODUTTORE DICHIARA DI ESSERE L'UNICO RESPONSABILE DEL RILASCIO DELLA DICHIARAZIONE DI CONFORMITÀ UE.
THE MANUFACTURER HEREBY DECLARES THAT HE IS SOLELY RESPONSIBLE FOR ISSUING THE EU DECLARATION OF CONFORMITY.

IL FABBRICANTE DICHIARA INOLTRE CHE IL DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO:
THE MANUFACTURER FURTHER STATES THAT THE IN VITRO DIAGNOSTIC DEVICE:

Nome commerciale: Trade name:	**Cube Reader**
Versions:	**Flat; Cavity**
Basic-UDI-DI:	**42520204CUBEDQ**

CON IL SEGUENTE SCOPO:
WITH THE FOLLOWING PURPOSE:

Fotometro destinato alla misurazione qualitativa, semiquantitativa o quantitativa della densità ottica delle linee sulle strisce reattive utilizzate nei test a flusso laterale (LFA)/test rapidi per la diagnostica in vitro. La sua funzione è in particolare quella di fornire un ausilio diagnostico in relazione a specifici test LFA/reagenti; il materiale campione per questi test può essere qualsiasi fluido ed estratto corporeo. Il rilevamento di una malattia, disturbo o fattore di rischio di interesse dipende dal test definito dal produttore del reagente, che lo inserisce nel fotometro utilizzando una scheda RFID. Il produttore del reagente determina anche la popolazione target associata. L'applicazione viene eseguita esclusivamente manualmente da utenti professionali. Il fotometro in sé non è uno strumento diagnostico di accompagnamento alla terapia.

Photometer, intended for the qualitative, semi-quantitative or quantitative measurement of the optical density of lines on test strips used in Lateral Flow Assays (LFAs) / rapid tests for in-vitro diagnostics. In particular, its function is to provide diagnostic assistance in connection with specific LFA tests, sample material for these tests can be any body fluids and extracts. The evidence of a specific disorder, condition, or risk factor of interest depends on the test defined by the manufacturer of the assay reagents, who brings this test into the photometer via use of an RFID card. The manufacturer of the assay reagents also determines the related target population. The application is solely performed manually by professional users. The photometer itself is not a companion diagnostic device.

NONCHÉ I SOFTWARE CLASSIFICATI COME ACCESSORI DELL'IVD:
AS WELL AS THE SOFTWARE CLASSIFIED AS AN ACCESSORY TO THE IVD:

Nome del software: Software name:	**Cube DataReader Software**
Basic-UDI-DI:	**42520204CUBE-SW4T**

CON IL SEGUENTE SCOPO:
WITH THE FOLLOWING PURPOSE:

Accessori software (PC); Da utilizzare solo in combinazione con Cube Reader; Consente l'esportazione dei dati dei risultati dal lettore al PC e il controllo del lettore tramite il software tramite PC

Software accessory (PC); Only to be used in combination with Cube Reader; Allows result data export from reader to PC and control of the reader through the software via the PC

SONO CLASSIFICATI COME SEGUE SECONDO IL REGOLAMENTO (UE) 2017/746 SUI DISPOSITIVI MEDICO-DIAGNOSTICI IN VITRO (IVDR):
ARE CLASSIFIED AS FOLLOWS ACCORDING TO THE IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (EU) 2017/746 (IVDR):

- ☒ **Classe A, Allegato VIII, Regola 5 b / Device of Class A, Annex VIII, Rule 5 b**
- ☐ Classe B, Allegato VIII, Regola … / Device of Class B, Annex VIII, Rule …
- ☐ Classe C, Allegato VIII, Regola … / Device of Class C, Annex VIII, Rule …
- ☐ Classe D, Allegato VIII, Regola … / Device of Class D, Annex VIII, Rule …

E RISPETTARE TUTTI I REQUISITI APPLICABILI DEL REGOLAMENTO SUI DISPOSITIVI DIAGNOSTICI IN VITRO (UE) 2017/746 (IVDR).

AND COMPLY WITH ALL REQUIREMENTS OF THE IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (EU) 2017/746 (IVDR) THAT APPLY.

Specifiche tecniche comuni applicate: Applied common technical specifications:	**N/A (nessuna ancora pubblicata / none published yet)**
Procedura di valutazione della conformità:: Conformity assessment procedure:	**(EU) 2017/746 (IVDR); Art. 17 & Annex II, Annex III**
Organismo notificato (se consultato): Notified Body (if consulted):	**N/A**

Firma:
Signature:

X

Geschäftsführer / General Manager
Signiert von: Lutz Melchior

.....

Direttore Generale / General Manager

Berlin, 2023-12-01

Luogo, data / Place, date

Nome e funzione presso Chembio Diagnostics GmbH /
Name and function at Chembio Diagnostics GmbH