

|                          |                |                                                                           |                                                                                     |
|--------------------------|----------------|---------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| F MDR A-IV EN            |                | Technical Documentation<br>Respiratory physiotherapy products (Class IIa) |  |
| Issue date<br>2024-07-16 | Page<br>1 of 2 | Declaration of conformity                                                 |                                                                                     |



**KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE**  
**DECLARATION OF CONFORMITY / DICHIARAZIONE DI CONFORMITA**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |            |                                                                                                                                                                                                         |          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| <b>Name und Adresse der Firma</b><br>Nom et adresse de l'entreprise<br>Nome e indirizzo della ditta<br>Name and address of the firm                                                                                                                                                                                                                                                                                                                                                                  |            | <b>CEGLA Medizintechnik GmbH</b><br>Horresser Berg 1<br>56410 Montabaur                                                                                                                                 |          |
| <b>Single Registration Number (SRN)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                              |            | DE-MF-000010609                                                                                                                                                                                         |          |
| <b>Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que /</b><br><b>Dichiariamo sotto nostra responsabilità che / We declare under our sole responsibility that</b>                                                                                                                                                                                                                                                                                  |            |                                                                                                                                                                                                         |          |
| <b>das Medizinprodukt mit seiner Zweckbestimmung</b><br>le dispositif médical avec sa destination<br>il dispositivo medico con la sua destinazione d'uso<br>the medical device with its intended use                                                                                                                                                                                                                                                                                                 |            | <b>Atemphysiotherapieprodukte gem. angehangener Produktliste</b><br>Respiratory physiotherapy products acc. to attached product list                                                                    |          |
| <b>entsprechend dem Ausgabestand der technischen Dokumentation</b><br>selon la révision de la documentation technique<br>secondo la revisione della documentazione tecnica<br>according to the revision of the technical documentation                                                                                                                                                                                                                                                               |            | 2024-07-16                                                                                                                                                                                              |          |
| <b>mit der Basis-UDI-DI</b><br>avec la base-UDI-DI<br>con la base-UDI-DI<br>with the basis-UDI-DI                                                                                                                                                                                                                                                                                                                                                                                                    |            | 4011371RC-CornetFamilieG5                                                                                                                                                                               |          |
| <b>der Klasse</b><br>de la classe<br>della classe<br>of class                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>IIa</b> | <b>nach Anhang VIII MDR 2017/745 – Regel</b><br>selon l'annexe VIII de la MDR 2017/745 – règle<br>secondo l'allegato VIII della MDR 2017/745 – regola<br>according to annex VIII of MDR 2017/745 - rule | <b>5</b> |
| <b>allen Anforderungen der MDR 2017/745 entspricht, die anwendbar sind. /</b><br>remplit toutes les exigences de la MDR 2017/745 qui le concernent. /<br>soddisfa tutte le disposizioni della MDR 2017/745 che lo riguardano. /<br>meets all the provisions of the MDR 2017/745 which apply to it.                                                                                                                                                                                                   |            |                                                                                                                                                                                                         |          |
| <b>Konformitätsbewertungsverfahren</b><br>Procédure d'évaluation de la conformité<br>Procedimenti di valutazione della conformità<br>Conformity assessment procedure                                                                                                                                                                                                                                                                                                                                 |            | MDR Art. 52 & Annex IX<br>(ohne Kapitel II, sans chapitre II, without chapter II, senza il capitolo II)                                                                                                 |          |
| <b>Notified Body</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |            | <b>0483</b><br><b>mdc medical device certification GmbH</b><br>Kriegerstraße 6<br>D-70191 Stuttgart                                                                                                     |          |
| <b>Gültigkeit der Erklärung: bis 2028-08-15 (Gültigkeit des CE Zertifikates) oder Änderungen der technischen Dokumentation /</b><br>Validité de la déclaration: à 2028-08-15 (validité du certificat CE) ou modifications de la documentation technique /<br>Validità della dichiarazione: a 2024-08-15 (validità del certificato CE) o modifiche alla documentazione tecnica /<br>Declaration's validity: to 2024-08-15 (validity of the EC certificate) or changes to the technical documentation. |            |                                                                                                                                                                                                         |          |

