

# DECLARATION OF CONFORMITY

Hartwell Medical LLC  
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**Type of Device:** Scoop Stretcher/Extrication Board Head Support

**Device Name:** CombiCarrierII® Head Immobilizer  
**Basic UDI-DI:** 0850012936CC7G

**Model Numbers:** CC 3400H  
CC 3400H-BK

**Parts:** CC 3400-9-100 CC 3400-9-100-BK  
CC 3400-9-200 CC 3400-9-200-BK  
CC 3400-9-300 CC 3400-9-300-BK

**Intended Purpose** Stabilization of the head during extrication, transfer, and transport.

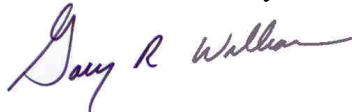
**Risk Class** I (Annex VIII, Rule 1)

**Conformity Assessment Route** Annex IV  
Self Certification

**EC Representative** Emergo Europe (SRN: NL-AR-000000116)  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

**We herewith declare that the above-mentioned products provided with CE marking meet the General Safety and Performance Requirements of Regulation 2017/745. This declaration is issued under the sole responsibility of Hartwell Medical LLC.**

Attested this 24th day of May 2021 at Hartwell Medical LLC in Carlsbad, California.



**Gary R. Williams**  
President and CEO