

# Ortho Clinical Diagnostics

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## Letter of Explanation

To whom it may concern:

We, Ortho-Clinical Diagnostics, Inc., located at 1001 US Highway 202, Raritan, New Jersey 08869 USA, hereby declare the below information for our product "ORTHO™ 7% BSA" manufactured by us as follows.

### ***Manufacturing Site:***

Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive, Rochester, New York 14626, U.S.A.

### ***Codes:***

6844285 ORTHO™ 7% BSA – 12 x 5mL  
6986722 ORTHO™ 7% BSA – 15 x 12mL

### ***Intended Use:***

Sec. 864.4010 General purpose reagent.  
(a) A general purpose reagent is a chemical reagent that has general laboratory application, that is used to collect, prepare, and examine specimens from the human body for diagnostic purposes, and that is not labeled or otherwise intended for a specific diagnostic application.

### ***Classification:***

The ORTHO™ 7% BSA is classified as a general purpose reagent not an In Vitro Diagnostic Medical Device and thus is not CE marked. There is no Declaration of Conformity.

Nazira Bhayan-Dada  
Regulatory Affairs Manager

March 5, 2019  
Date